

# EXHIBIT A

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ALLERGAN USA, INC., ALLERGAN	)	
HOLDINGS UNLIMITED COMPANY, and	)	
EDEN BIODESIGN, LLC,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 1:19-1727 (RGA)
	)	
AUROBINDO PHARMA LTD.,	)	
AUROBINDO PHARMA USA, INC.,	)	
ALKEM LABORATORIES LIMITED,	)	
HETERO LABS LIMITED, HETERO USA	)	
INC., MSN LABORATORIES PRIVATE	)	
LIMITED, MSN PHARMACEUTICALS,	)	
INC., SUN PHARMACEUTICAL	)	
INDUSTRIES LIMITED, and ZYDUS	)	
PHARMACEUTICALS (USA) INC.,	)	
	)	
Defendants.	)	

**[PROPOSED] STIPULATED PROTECTIVE ORDER**

Pursuant to Federal Rule of Civil Procedure 26(c)(1) and the Scheduling Order, Plaintiffs Allergan USA, Inc., Allergan Holdings Unlimited Company, and Eden Biodesign LLC (collectively “Allergan” or “Plaintiffs”) and Defendants Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. (collectively, “Aurobindo”), Alkem Laboratories Limited (“Alkem”), Hetero Labs Limited and Hetero USA Inc. (collectively, “Hetero”), MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc. (collectively, “MSN”), Sun Pharmaceutical Industries Limited (“Sun”), and Zydus Pharmaceuticals (USA) Inc. (“Zydus”) (collectively with Aurobindo, Alkem, Hetero, MSN, and Sun, “Defendants”), respectfully request that the following Stipulated Protective Order be entered in the above-captioned action (the “Proceeding”) to govern the exchange of discovery materials by the parties and third parties, the use or exhibition of documents and things, and the use or presentation of testimony containing trade secrets,

confidential or proprietary research, development, technical, financial, strategic, customer, or commercial information, as well as other kinds of commercially sensitive information within the meaning of Federal Rule of Civil Procedure 26(c)(1), and personal health information protected under state or federal privacy laws, or other applicable personal data protection laws or regulations.

Plaintiffs and Defendants (collectively, “the Parties”) agree, and this Court finds, that the disclosure of such commercially sensitive information poses a substantial risk of harm to the legitimate proprietary interests of the Parties and third parties. Therefore, good cause exists for entry of this Stipulated Protective Order to preserve the confidentiality of certain documents and information, to outline procedures and reasonable restrictions on the disclosure of sensitive materials, and to permit discovery to proceed without delay.

Accordingly, the Court hereby enters the following Stipulated Protective Order, which shall control the disclosure, dissemination, and use of information in these Proceedings:

**I. DESIGNATION OF MATERIAL AS “CONFIDENTIAL”**

1. The designation of material as “Confidential” as used in this Stipulated Protective Order means information (regardless of how it is generated, stored or maintained) or tangible things that qualify for protection under Federal Rule of Civil Procedure 26(c)(1), including but not limited to any data, projections, or other research, development, technical, commercial, or personnel information, practices, or methods that are non-public and confidential or proprietary, including but not limited to the types of documents set forth below. Identification of types of documents in this Paragraph shall not be an admission by any party that such documents are relevant or admissible in this Proceeding.

a. Commercial information, including without limitation, strategic plans, marketing and financial information (for example, P&L statements) concerning a party’s current

products, processes and/or business relationships or potential future products, processes and/or business relationships.

b. Confidential marketing plans, market research and business strategy, including research regarding competitors and projected future sales or pricing.

c. Names, or other information tending to reveal the identities, of a party's suppliers, present or prospective customers, or distributors.

d. Agreements with a party's suppliers, present or prospective customers, or distributors.

e. Revenue, cost, or profit information for a party's products.

f. Information relating to a party's research and development efforts.

g. Product specifications, formulations, and/or information regarding the manufacture of a party's products.

h. Technical notebooks and technical reports of a party, including product and manufacturing specifications, schematic diagrams, technical reference manuals, operations manuals, or other similar information.

i. Information that a party believes in good faith is a proprietary trade secret.

j. Information relating to pending patent applications.

k. New Drug Applications ("NDAs"), Abbreviated New Drug Applications ("ANDAs"), Drug Master Files ("DMFs"), and Premarket Approval Applications ("PMAs"), including correspondence with the FDA regarding any of the above.

l. Physical samples of any products, active pharmaceutical ingredients, placebos referenced and/or used for comparison, or excipients.

m. Personal information of a party's employees.

n. Personal information and/or identities of physicians and patients.

o. Information that any party is required to maintain in confidence under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) or any similar law or regulation.

p. Any other information a producing party believes in good faith could cause irreparable harm to its business if disclosed to personnel for the receiving party.

Confidential information may be contained in discovery information or materials produced or obtained in this Proceeding by or through any means and by or through any person or entity. The Confidential information contained therein, and all copies, recordings, abstracts, excerpts, analyses, or other writings that contain, reveal, or otherwise disclose such Confidential information, shall also be deemed Confidential information.

2. Any party or third party may designate as “Confidential” all or any part of any discovery or other materials produced or served in this Proceeding, or filed with the Court, including without limitation, documents and things, pleadings, motions, interrogatory answers, deposition testimony, and responses to requests for admission, which contain proprietary, business, financial, technical, or other confidential information or know-how protectable under Federal Rule of Civil Procedure 26(c)(1), as set forth in Paragraph 1 above.

3. A party or third party shall designate a document or thing as Confidential by marking it prominently on its face with the legend “CONFIDENTIAL” or “CONFIDENTIAL—SUBJECT TO PROTECTIVE ORDER,” as appropriate, when it is produced to the party seeking discovery. Anything that cannot be so marked on its face shall be marked by placing the appropriate legend on a container or package in which the thing is produced or on a tag attached thereto or on an accompanying production letter. If an entire

multi-page document is to be treated as Confidential, each page of such document should be marked. In addition, to the extent practicable, each page of each document and each thing produced pursuant to discovery in this Proceeding shall bear a unique identifying number.

4. Notwithstanding such designation, Confidential information does not include information obtained independently of this Proceeding as to which no obligation of confidentiality applies. Accordingly, nothing in this Order shall prevent any person, including a Qualified Person, from making use of any information that is designated as Confidential information if such information:

a. is determined by agreement of the Parties or order of the Court to be public information,

b. was lawfully in his or her possession prior to receiving the information or document under the provisions of this Order,

c. was, is, or becomes available to the public through no fault of a receiving party,

d. is disclosed by a third party who is not subject to any confidentiality obligations at the time of the disclosure, or

e. is discovered independently by the receiving party by means that do not constitute a violation of the law or this Order.

5. Nothing in this Order shall prevent a party or third party from redacting from documents or things, which otherwise contain relevant discoverable information, any Confidential information that is irrelevant to this Proceeding or otherwise not discoverable, such as information relating to a product not at issue in the Proceeding, pursuant Federal Rule of Civil Procedure 26(b). Redactions shall be clearly labeled as such, and nothing in this Paragraph shall

be construed as a waiver of any party's right to seek disclosure of redacted information. Redactions for privilege or immunity shall be marked as "Redacted Privilege" or a similar marking. Any materials marked with a "Redacted Privilege" designation are not required to be logged in a party's privilege log in the first instance. Upon a showing of good cause (*e.g.*, that the nature of the privilege claim cannot reasonably be ascertained), the receiving party may request that the producing party log a redacted document. Plaintiffs and Defendants need not log material in a privilege log to the extent that material was generated on or after July 31, 2019, the date on the face of the first notice letter that was received by Plaintiffs with respect to Viberzi®.

6. Prior to production, a party or third party may redact from all documents, e-mails, and personal electronic files all personal information, including the following: home address, home and cell phone numbers, pager numbers, names of spouses and children, credit card information, benefits information, compensation information, and information found in employee files.

7. Unless otherwise agreed by the Parties, deposition transcripts taken in connection with this Proceeding will be temporarily designated and treated as Confidential for thirty (30) calendar days from the date of the deposition, in order to give the Parties or third parties the opportunity to properly designate any Confidential information in the transcript. Within those thirty (30) calendar days, the Parties and/or third parties may designate any or all portions of the transcript as Confidential information in accordance with this Protective Order. If a deposition transcript or deposition exhibits contain Confidential information, the deposition transcript will be marked on its first page with the legend "CONFIDENTIAL -- SUBJECT TO PROTECTIVE ORDER." Nothing in this Order shall prevent a deponent from reviewing and making corrections to the transcript of their deposition pursuant to Federal Rule of Civil Procedure 30(e).

Nothing in this Paragraph shall prevent a party from showing to its own employees, officers, directors, or agents transcripts from depositions taken of its own witnesses.

8. Any documents or material provided for inspection, as opposed to produced, in this Proceeding is to be treated by the inspecting/receiving party as Confidential information pending the copying and delivery of any copies of the same by the producing party. After copies are delivered to the inspecting/receiving party, the information in such documents or things will be treated consistent with any legend on each document or thing. Unless otherwise agreed or ordered by this Court, inspection of documents or things by a party shall be conducted only by Outside Counsel or independent consultants or experts eligible under Paragraph 14(c) below.

9. For any documents produced before the entry of this Order and marked under District of Delaware Local Rule 26.2, the receiving party will treat them as Confidential after entry of this Order, unless the producing party subsequently designates them otherwise.

10. Documents and things produced without a legend designating the material Confidential shall not be subject to this Protective Order, unless otherwise agreed by the Parties or ordered by the Court.

## **II. USE OF CONFIDENTIAL INFORMATION**

11. Confidential information, including all copies, summaries, abstracts, excerpts, indices, and descriptions of such material, shall be held in confidence by the receiving party, shall be used only by persons permitted access to the information under this Protective Order, and shall not be used for any purpose other than in connection with this Proceeding, any appeal therefrom, and any remands thereto. For example, the Confidential information of another party shall not be used for any research, development, patent prosecution, patent claim amendments, commercial, marketing, regulatory (including Citizen Petitions), or other competitive purpose. All persons receiving Confidential information are expressly prohibited from using or disclosing



such information in connection with any practice before or communication with the United States Patent and Trademark Office (“USPTO”), the United States Food and Drug Administration (“FDA”), the United States Pharmacopoeia, or their counterpart organizations in any foreign jurisdiction. Nothing contained in this Order shall preclude any party from using its own Confidential information in any manner it sees fit, without prior consent of any party or the Court. Nothing in this Order shall restrict any party’s counsel from rendering advice to its clients with respect to this Proceeding and, in the course thereof, relying upon Confidential information, provided that in rendering such advice counsel shall not disclose any other party’s Confidential information other than in a manner provided for in this Order.

12. **[Plaintiffs’ Proposed Language:** Without prior written approval of the producing party, no outside counsel for any Defendant may disclose the Confidential information of any other Defendant to any designated in-house counsel or IP manager under Paragraph 14(b)(1) or (b)(2), respectively. Similarly, no Defendant shall intentionally request or, if inadvertent, demand that Plaintiffs produce to them any Confidential information previously produced to Plaintiffs by another Defendant.] / **[Defendants’ Proposed Language:** Without prior written approval of the producing party, which shall not be unreasonably withheld, or an order from the Court, no person permitted access to any Confidential information may disclose the Confidential information of one Defendant to any other Defendant; however, the parties shall consider disclosure of Confidential information among Defendants on an outside counsel basis when appropriate for litigation efficiency and Confidential information of a Defendant may be used by Plaintiffs at any Court hearing or trial or at any appeal thereof, even if outside counsel of any of Defendant is present.]

13. The Defendants in this Proceeding, as well as any defendants who join or are joined to this Proceeding and who are bound by this Protective Order, may exchange documents or information (including, but not limited to, motions, briefs, declarations, discovery responses, contentions, and expert reports) describing or referring to information designated by Plaintiffs as Confidential, so long as every Defendant who receives such documents treats all designated materials in accordance with this Protective Order. The exchange contemplated by this Paragraph does not modify any of the restrictions on the dissemination of Plaintiffs' Confidential information set forth in this Protective Order.

### III. ACCESS TO CONFIDENTIAL INFORMATION

14. Confidential information may be disclosed only to the following “Qualified Persons:”

a. When Plaintiffs are the non-designating parties, up to two (2) in-house counsel, provided that each in-house counsel is a licensed U.S. attorney and is not directly responsible for competitive decision making and provides Defendants' counsel with a copy of a signed Undertaking in the form of Exhibit A, along with their necessary secretarial, clerical, paralegal, and other supporting personnel. For Plaintiffs, these in-house legal counsel shall be:

Allergan: Casey Dwyer and Michael Montgomery

b. 1. When Defendants are the non-designating parties, up to two (2) in-house counsel, provided that each in-house counsel is a licensed U.S. attorney and is not directly responsible for competitive decision making and provides Plaintiffs' counsel with a copy of a signed Undertaking in the form of Exhibit A, along with their necessary secretarial, clerical, paralegal, and other supporting personnel. For Defendants, these in-house counsel shall be:

Aurobindo: \_\_\_\_\_

Alkem: [REDACTED]

Hetero: \_\_\_\_\_

MSN: \_\_\_\_\_

Sun: \_\_\_\_\_

Zyklus: \_\_\_\_\_;

2. To the extent that a Defendant does not have two in-house legal counsel who meet the above criteria in their corporation or corporate family, then such Defendant may disclose Confidential information to up to two in-house IP managers, such that the Defendant in question has no more than two individuals authorized to receive and review Confidential information in connection with the Proceeding, so long as each such IP manager is not directly responsible for competitive decision making and provides Plaintiffs' counsel with a copy of a signed Undertaking in the form of Exhibit A. For Defendants, these in-house IP managers shall be:

**Aurobindo:** \_\_\_\_\_

Alkem: Amaresh Panda and Vinod Sawant;

Hetero: \_\_\_\_\_

MSN: Kondal Reddy Bairy

Sun:  

Zyklus: \_\_\_\_\_;

c. Independent experts and consultants and their staff retained to assist counsel for the Parties in the conduct of this Proceeding, provided such experts and consultants have complied with Paragraphs 18 and 19 herein;

d. The Court and its law clerks, staff, and any jury selected to hear this case;

e. Court reporters and videographers;

f. Photocopy services;

g. Professional translators who are retained by the attorneys for the Parties for the purposes of these litigations;

h. Graphics or design consultants retained to prepare demonstrative or other exhibits for use in this action;

i. Non-technical trial consultants and persons employed or retained by them;

j. Document imaging and database services and consultants retained to set up, maintain and/or operate litigation databases; and

k. Others as to whom the designating party has given written consent.

15. During the Proceedings, and for a period of one year following their conclusion, including any appeal or remand, any person receiving Confidential information may not participate in any ex parte patent prosecution proceedings before the USPTO involving eluxadoline or any polymorph or formulation thereof, or any corresponding ex parte patent prosecution proceedings before any corresponding foreign patent or regulatory authority. Similarly, during the Proceedings, and for a period of one year following their conclusion, including any appeal or remand, any person receiving Confidential information may not participate in any portion or phase of any inter partes review (“IPR”) proceedings or ex parte reexamination proceedings before the USPTO directed to amending patent claims, or any corresponding proceedings before any corresponding foreign patent or regulatory authority.

16. Only Qualified Persons, the deponent, and his or her attorney (if any), shall be allowed to attend any portion of a deposition during which Confidential information is used or elicited from the deponent. Counsel for the designating party may request that all persons other than the deponent, the court reporter and videographer, Qualified Persons, individuals specified in Paragraph 14, and counsel for the witness (if a third party witness) leave the deposition room

during any portion of a deposition which enquires into matters deemed Confidential by the designating party. The failure of individuals other than those specified in the previous two sentences to leave the deposition room during any portion of the deposition which enquires into matters deemed Confidential information by the designating party shall constitute justification for counsel to instruct the witness that he or she shall not answer the question(s) posed concerning such matters until such time as all individuals other than those specified in the previous two sentences leave the deposition room.

17. This Order shall not limit a party's examination, at a deposition, hearing, or trial, of persons who are not authorized to receive Confidential information under the terms of this Order, so long as such examination concerns only Confidential information that the witness authored, received, was involved in generating, or previously had access to or knowledge of, as demonstrated by the information itself or by foundation testimony during a deposition, hearing, or trial, or if the producing party consents to such disclosure. This Order shall not prevent counsel from examining a witness in a good-faith effort to determine whether he or she authored, received, generated, or previously had access to or knowledge of Confidential information. Examination using a party's Confidential information may be conducted on a witness of the same party who is a designee pursuant to Federal Rule of Civil Procedure 30(b)(6).

18. Before disclosing another party's Confidential information to a person or entity described in Paragraph 14(c), the party shall first obtain a signed Certification in the form of the annexed Exhibit B. The Certification shall be signed by the company, firm, group, or person retained by the party, and a single Certification by the company, firm, group, or person shall be sufficient to cover all employees of the company, firm, or group. Counsel retaining the person(s) described in Paragraph 14(c) shall retain the original of each such signed Certification.

19. Before disclosing another party's Confidential information to an outside consultant or expert under Paragraph 14(c), the party shall first provide to the producing party: (a) a signed copy of the Certification found in Exhibit B of this Order; (b) a current resume (curriculum vitae) for the consultant or expert including a list of publications; and (c) a list of any other cases in which the consultant or expert has testified as an expert at trial or by deposition within the preceding four (4) years. Once the producing party has received the requisite documents and consultant/expert information, the producing party shall then have seven (7) calendar days to provide a written objection to the proposed disclosure of its Confidential information, including the specific reason(s) for such objection. No disclosure of Confidential information shall occur during this 7-day period. If a timely written objection is made: (i) there shall be no disclosure of the Confidential information to the consultant or expert, except by further order of the Court or by agreement by the Parties, (ii) the Parties agree to promptly meet and confer in good faith regarding the basis for (and resolution of) the objection, and (iii) if the Parties cannot reach an agreement, the party objecting to the disclosure of information to the consultant/expert may pursue the issue via the Court's established discovery dispute procedures within seven (7) calendar days of the meet and confer. On any motion brought pursuant to this Paragraph, the objecting party shall bear the burden of showing why disclosure of information to that consultant/expert should be precluded. Failure to timely object or to timely seek adjudication by the Court will act as a waiver of the objection, and the consultant or expert will become a Qualified Person.

20. Any person who receives Confidential information pursuant to Paragraph 14 may not during the pendency of this Proceeding and for a period of one year after final termination of the Proceeding, including any appeals or remands, have direct responsibility in any petitioning,

counseling, or other correspondence involving the FDA concerning Viberzi® and/or any proposed therapeutic equivalents thereof (e.g., concerning any methods of use or administration of Viberzi® or determination of bioequivalence to Viberzi® or determination of abuse deterrence for any proposed generic version of Viberzi®), including but not limited to the preparation or submission of any FDA correspondence (e.g., citizen's petitions and oppositions to citizen's petitions), or any similar correspondence in any foreign country regarding regulatory approval requirements for Viberzi®. For avoidance of doubt, nothing in this Paragraph shall be construed to limit the individual from communicating with FDA or any other regulatory or governmental authority in good faith regarding health, safety or efficacy matters related to Viberzi® and/or any proposed therapeutic equivalents thereof, pursuant to court order, or as otherwise requested by the FDA or required by applicable law or regulation.

21. If, at the time this Order is signed, a party has not yet identified each of the individuals permitted by Paragraph 14, it may designate such personnel provided it serves written notification to all producing parties along with an Undertaking in the form of Exhibit A attached hereto. Additionally, a party wishing to substitute any personnel permitted by Paragraph 14 may do so for good cause (*e.g.*, an attorney or IP manager leaving the company), so long as the party serves written notice to all producing parties along with any necessary Undertaking in the form of Exhibit A attached hereto.

#### **IV. INADVERTENT PRODUCTION OF UNDER-DESIGNATED MATERIAL**

22. Inadvertent production of any document, thing, or information without a designation of Confidential information will not be deemed to waive a later claim as to its confidential nature, or stop the producing party from designating said document or information as Confidential information at a later date.

23. Any producing party may change a designation to Confidential (or withdraw a designation) regarding any material that it has produced by notifying counsel for each receiving party in writing. Upon receipt of such notice, the non-producing party shall: (i) not make any further disclosure or communication of such newly designated material except as provided for in this Order; (ii) take reasonable steps to notify any persons known to have possession of any material with the original designation (or lack of designation) and alert those persons of the effect of such a change in designation under this Order; (iii) for material newly designated as Confidential, promptly retrieve or have destroyed all copies and transcriptions of such originally designated (or undesignated) material from any persons known to have possession of such material who are not specified in Paragraph 14. Properly marked documents, reflecting the new designation, shall be promptly provided by the producing party.

#### **V. CHALLENGING A “CONFIDENTIAL” DESIGNATION**

24. A party receiving documents or things shall not be obligated to challenge the propriety of a Confidential information designation (or re-designation) at the time the document or thing is produced, and a failure to do so shall not preclude a subsequent challenge thereto. If a receiving party disagrees at any time with a Confidential information designation made by another party or a third party, the following procedure shall be used:

a. The party seeking to change the designation of another party's documents, things, or information shall provide the producing party written notice specifying the documents, things, or information for which a change in designation is sought, and the reasons for the request. The producing party shall have seven (7) calendar days after receipt of the written notice within which to object in writing to the change in designation or removal of protection afforded by this Order and to specify why protection under this Order is appropriate.



b. If the producing party objects in writing within seven (7) calendar days of receiving such a written notice, the Parties shall meet and confer in an attempt to resolve the dispute without involvement of the Court.

c. If the Parties and/or third parties cannot reach agreement concerning the change in designation, the party seeking the removal of protection for the Confidential information may pursue the issue via the Court's established discovery dispute procedures.

d. The Parties shall continue to treat the document(s) or thing(s) at issue as Confidential information (according to the original designation(s)) until the dispute is resolved by Order of this Court, or by agreement of the Parties and/or third parties.

e. On any motions arising out of the designation of any material as Confidential information under this Order, the burden of justifying the designation shall lie with the producing party.

## **VI. INADVERTENT USE OF CONFIDENTIAL INFORMATION**

25. If any Confidential information of another party is inadvertently used by a receiving party during the course of the Proceeding (including at a deposition) in a manner that contravenes this Stipulated Protective Order, the information shall not lose its confidential status as a result of such use.

26. If any Confidential information is inadvertently disclosed to any person other than in the manner authorized by this Stipulated Protective Order, the party responsible for the inadvertent disclosure shall, within two (2) calendar days of learning of such disclosure, inform the producing party of such disclosure in writing. As soon as practicable thereafter, the party responsible for the inadvertent disclosure shall use reasonable efforts to obtain the prompt return or destruction of any such Confidential information, and obtain a signed Certification in the form attached hereto as Exhibit B from each unauthorized person or party who inadvertently received

any Confidential information. Satisfaction of the requirements set forth in this Paragraph shall not prevent the producing party from seeking any additional relief, whether by agreement of the Parties or order of the Court.

## **VII. INADVERTENT PRODUCTION OR USE OF PRIVILEGED INFORMATION**

27. If information subject to a claim of attorney-client privilege, attorney work product immunity, or other legal privilege protecting information from discovery is inadvertently produced in any way, such production shall not constitute a waiver (subject matter or otherwise) of any claim of attorney-client privilege, attorney work product immunity, or other legal privilege or ground for withholding production to which the producing party, third party, or other person otherwise would be entitled. The protections afforded such inadvertent production herein shall be at least as protective as those provided in Fed. R. Civ. P. 26(b)(5)(B) and/or Fed. R. Evid. 502.

28. If a written claim of inadvertent production of privileged information is made by a producing party to a receiving party, the receiving party shall:

a. immediately upon receipt of the claim not make any further copies, reproductions, or transcriptions of the inadvertently disclosed information or document; if the inadvertent disclosure is discovered during a deposition, the claim for inadvertent production may be made orally, and upon such oral claim all copies of the requested document physically at the deposition must be immediately returned to counsel for the producing party present at the deposition; and

b. within five (5) days of receipt of the claim described in Paragraph 28(a), destroy or return to the producing party every original and every copy, reproduction, or transcription of all such inadvertently produced information or documents possessed by the

receiving party and by those persons to whom the receiving party may have disclosed such information.

29. Recognizing the need for the Parties to prepare for their case based on the discovery that is produced, if any information, document, or thing is used openly in the case, e.g., at a court hearing, in a deposition, as an exhibit to a motion, or is referenced in an expert report or pretrial order, any claim of inadvertent production based on privilege, must be made within two (2) weeks after such use.

30. Nothing herein shall prevent a receiving party from challenging the propriety of any claim of attorney-client privilege, work product immunity, or other privilege designation for any inadvertently produced document, except that the inadvertent disclosure shall not be a basis for any such challenge. The producing party shall maintain for the duration of the Proceeding a copy of any inadvertently produced document for which it made a subsequent claim of attorney-client privilege, work product immunity, or other privilege. Despite the existence of a challenge, any inadvertently produced document that is returned based on a claim of attorney-client privilege, work product immunity, or other privilege shall be treated as if it were properly covered by the asserted attorney-client privilege, work product immunity, or other privilege unless and the challenge is resolved in favor of the receiving party.

#### **VIII. INADVERTENT PRODUCTION OF ELECTRONICALLY STORED INFORMATION**

31. If electronically stored information (“ESI”) is inadvertently produced as the result of an error in the ESI production process, including but not limited to predictive coding errors, optical character recognition (“OCR”) errors, or errors in the application of search terms to ESI databases, such production shall not constitute a waiver (subject matter or otherwise) of any claim of privilege, work product immunity, or other ground for withholding production to which

the producing party, third party, or other person otherwise would be entitled. The protections afforded inadvertent production herein shall be at least those provided in Fed. R. Civ. P. 26(b)(5)(B) and/or Fed. R. Evid. 502.

32. If a written claim of inadvertent production of ESI is made by a producing party to a receiving party, the receiving party shall:

a. immediately upon receipt of the claim not make any further copies, reproductions, or transcriptions of the inadvertently disclosed ESI; if the inadvertent disclosure is discovered during a deposition, the claim for inadvertent production may be made orally, and upon such oral claim all copies of the requested ESI physically at the deposition must be immediately returned at the deposition; and

b. within five (5) days of receipt of the claim described in Paragraph 32(a), destroy or return to the supplying party every original and every copy, reproduction, or transcription of all such inadvertently produced ESI possessed by the receiving party and by those persons to whom the receiving party may have disclosed such information.

33. Recognizing the need for the Parties to prepare for their case based on the discovery that is produced, if any ESI is used openly in the case, e.g., at a court hearing, in a deposition, as an exhibit to a motion, or is referenced in an expert report or pretrial order, any claim of inadvertent production of such ESI must be made within two (2) weeks after such use.

34. Nothing herein shall prevent the receiving party from challenging the propriety of the claim of inadvertent production of ESI. The receiving party must preserve the confidentiality of the document or information until the claim is resolved.

## **IX. PRODUCTION OR DISCLOSURE OF A THIRD PARTY'S INFORMATION**

35. Any subpoena or other notice to a third party requesting production of documents shall include a copy of this Protective Order. This requirement shall not change the requirements for service of a valid subpoena under the Federal Rules of Civil Procedure.

36. If a third party produces documents pursuant to a subpoena or other request issued by one of the Parties (or by Court order) and if the third party has not requested its documents be treated as Confidential, then it shall be presumed that the documents produced contain information for which the third party has determined require no designation under the Stipulated Protective Order. The third party's documents and things shall be handled by all Parties to this Proceeding according to the appropriate designations under this Stipulated Protective Order. The party issuing the subpoena or other request for documents or things to the third party shall provide any non-requesting party an opportunity to review and make copies of any documents produced in response to that subpoena or request.

37. A party in this Proceeding may temporarily withhold production of otherwise discoverable information sought in a discovery request (e.g., interrogatory, request for production, request for admission) if the party is under an obligation to a third party not to disclose such information (e.g., by prior agreement of confidentiality). In such an event (except for information subject to another protective order or confidentiality order by another court), the producing party shall:

- a. timely serve a written objection to the production of the requested information on the basis of its obligation to a third party not to disclose such information;
- b. promptly provide to the third party whose confidentiality interests are implicated (i) notice of the pending request to disclose the information, and (ii) a copy of this Protective Order; and

c. if the third party does not agree to disclosure of its information, then the party requesting the documents or things from the third party may (i) serve a subpoena on the third party, if the requesting party has not already done so, or (ii) file a motion to compel production of the requested documents against a party and/or third party in the appropriate Court.

38. Any party to this Proceeding that receives a subpoena or other request from a third party that seeks the disclosure/production of Confidential information already disclosed in this Proceeding that the party did not itself produce shall give prompt telephonic and written notice to that original producing party of such subpoena or other request, but in no event more than seven (7) calendar days after actual receipt of the subpoena or other request. If the original producing party opposes disclosure of its documents called for by the subpoena or other request within seven (7) calendar days from notice of the subpoena, then the party served with the subpoena shall not disclose the pertinent information until a Court has resolved the issue. Absent a Court order, production or disclosure of another party's information shall not be made until the original producing party has agreed to such production to a third party. The original producing party shall bear the burden to oppose, if it deems appropriate, the subpoena or other request on the grounds of confidentiality. This Paragraph shall not apply to disclosure of information pursuant to a third party's subpoena or request for Confidential information, if the party receiving the subpoena or request itself produced the documents or things called for by the subpoena or request, i.e., this Paragraph shall not apply to the disclosure of a party's own documents or things.

**X. USE OF CONFIDENTIAL INFORMATION IN FILINGS AND IN OPEN COURT**

39. Nothing herein shall be construed to affect in any manner the admissibility at trial of any document, testimony, or other evidence.

40. The Clerk of Court is directed to maintain under seal any pleading, motion, brief, memorandum, exhibit, affidavit, declaration, transcript, response to a discovery request, or other paper filed with the Court in compliance with Local Rule 5.1.3, which has been designated, in whole or in part, as containing or revealing Confidential information under this Stipulated Protective Order.

41. In the event that a party or third party wishes to use any Confidential information in any pleading, motion, brief, memorandum, exhibit, affidavit, declaration, transcript, response to a discovery request, or other paper filed with the Court to be maintained under seal, such paper shall be filed according to Local Rule 5.1.3.

42. Any health information that is protected under state or federal privacy laws and is disclosed in discovery by a party or third party to this Proceeding shall not be used or disclosed in open court unless in accordance with a further order of the Court, such as an order of the Court sealing the courtroom. The Court will enter further orders as necessary to control the conduct of hearings and trial as it relates to the use of Confidential information.

#### **XI. DISPOSITION OF CONFIDENTIAL MATERIALS AFTER CONCLUSION OF THIS PROCEEDING**

43. Upon the final non-appealable termination of this Proceeding, all Confidential information received from an opposing or third party (and all copies and transcriptions thereof), shall be destroyed or returned to the producing party within ninety (90) calendar days. Outside Counsel, however, may retain (even if such documents or things contain Confidential information) all correspondence, pleadings and exhibits, deposition transcripts and exhibits, expert reports and exhibits, hearing and trial transcripts and exhibits, court-filed documents and exhibits, and all documents and things containing or reflecting attorney work product except for HIPAA information (as defined in Paragraph 1), which must be destroyed or returned within

ninety (90) calendar days of the termination of this Proceeding. Outside Counsel shall certify their compliance with the provisions of this Paragraph within ninety (90) calendar days of the termination of the Proceeding. The producing party shall identify to the receiving party all such protected health information to be destroyed or returned by specific production numbers within forty five (45) calendar days of the termination of this Proceeding. If the producing party does not provide this specific information to the receiving party within forty five (45) days, then the receiving party is under no obligation to destroy or return the protected health care information, but the health care information shall remain Confidential under the provisions of this Order. Documents and work product retained by Outside Counsel shall remain subject to the terms of this Order. Pursuant to this Paragraph, after ninety (90) calendar days following final non-appealable termination of this Proceeding, no person or entity other than Outside Counsel shall retain any Confidential information that it received from another party during the course of the Proceeding, including but not limited to Confidential information in the form of notes, recordings, memoranda, summaries or other written materials relating to or containing another party's Confidential information.

44. To the extent a party is dismissed from the Proceeding prior to a final non-appealable termination with regard to the remaining parties, the dismissed party shall comply with Paragraph 43 as if the dismissal were a final non-appealable termination.

## **XII. ADDITIONAL PROVISIONS**

45. This Order shall be binding upon the Parties to this Proceeding and any signatories to the Undertaking attached as Exhibit A or the Certification attached as Exhibit B, including their successor(s) and assigns, and their respective attorneys, agents, representatives, officers, and employees.



46. This Order shall apply to all information and material produced in this Proceeding, including all information and material produced prior to the execution of this Order by the Court.

47. The Parties agree that the following documents will not be discoverable: (a) drafts of expert reports, affidavits, or declarations; (b) counsel's communications with experts, affiants or declarants, except to the extent such communications are excepted by Federal Rule of Civil Procedure 26(b)(4)(C)(i)-(iii); (c) experts', affiants', and declarants' notes and working papers regarding such documents; and (d) attorney-client communications dated on or after July 30, 2019, the date on the face of the first notice letter that was received by Plaintiffs with respect to Viberzi®.

48. If any party breaches, or threatens to commit a breach, of any of the provisions of this Order, each non-breaching party or third party that produced information subject to this Order shall have the right to ask the Court for any remedies available under law or in equity, including having the Order specifically enforced (without posting any bond) and/or entering a restraining order or injunction (preliminary or permanent) against the breaching party for breaches, threatened or actual. It is agreed and acknowledged that, in the event of any such breach or threatened breach, the breaching party is not entitled to a presumption that money damages or legal remedies are sufficient or adequate to remedy such a breach.

49. By written agreement of the Parties, or upon motion and order of the Court, the terms of this Order may be amended or modified, provided that any such stipulated modification concerning the use of any health information that is protected under state or federal privacy laws, or other applicable personal data protection laws, and is disclosed in discovery by a party or third party to this Proceeding shall be presented to the Court.

50. This Order shall continue in force until amended or superseded by express order of the Court. This Order shall survive termination of this Proceeding, including any final judgment, appeal, or settlement to the extent the Confidential information is not or does not become known to the public by means other than a breach of this Order.

51. Nothing in this Order shall prejudice the right of any party or third party to oppose production of any information for lack of relevance, privilege, or any ground other than confidentiality.

52. In the event that a new party is added, substituted, or otherwise brought into this Proceeding, this Protective Order will be binding on and inure to the benefit of the new party, subject to the right of the new party to seek relief from or modification of this Protective Order.

53. Each person or entity who receives any Confidential information agrees to subject himself/herself to the jurisdiction of this Court for the purpose of any proceedings relating to the performance under, compliance with, or violation of this Protective Order.

54. By entering this Order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this Order who becomes subject to a motion to disclose another party's information designated Confidential pursuant to this Order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

55. In order to expedite the discovery process, until this Stipulated Protective Order has been entered by the Court, the Parties agree that after counsel for the Parties execute this Stipulated Protective Order, it will be treated as though it had been "So Ordered."

SO ORDERED this \_\_\_\_ day of \_\_\_\_\_, 2020

---

The Honorable Richard G. Andrews  
United States District Judge

**EXHIBIT A**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

ALLERGAN USA, INC., ALLERGAN  
HOLDINGS UNLIMITED COMPANY and  
EDEN BIODESIGN, LLC,

Plaintiffs,

v.

AUROBINDO PHARMA LTD.,  
AUROBINDO PHARMA USA, INC.,  
ALKEM LABORATORIES LIMITED,  
HETERO LABS LIMITED, HETERO USA  
INC., MSN LABORATORIES PRIVATE  
LIMITED, MSN PHARMACEUTICALS,  
INC., SUN PHARMACEUTICAL  
INDUSTRIES LIMITED and ZYDUS  
PHARMACEUTICALS (USA) INC.,

Defendants.

C.A. No. 1:19-cv-01727-RGA

**UNDERTAKING REGARDING PROTECTIVE ORDER**

1. I, \_\_\_\_\_, have been asked by counsel for Plaintiffs / Defendant(s) [circle one] \_\_\_\_\_ (the “Identified Party(ies),” herein) in the above-captioned matter to review certain confidential documents or other information that is subject to the Stipulated Protective Order that has been or will be entered by the U.S. District Court for the District of Delaware in the above-captioned case.

2. My present employer is \_\_\_\_\_ and my present work address is \_\_\_\_\_. My present job title/description is \_\_\_\_\_.

3. I represent that:

a. I am an attorney licensed in the United States, or

b. after a reasonable investigation, the Identified Party(ies) and their corporate parents and corporate affiliates, collectively, do not employ two in-house legal counsel who are licensed U.S. attorneys and who are not directly responsible for competitive decision making.

4. I am not personally involved in competitive decision making on behalf of the Identified Party(ies).

5. I am not personally involved in the formulation of any drug product that is a generic equivalent of any drug containing eluxadoline and I do not have direct responsibility in any petitioning, counseling, or other correspondence involving the FDA concerning Viberzi® and/or any proposed therapeutic equivalents thereof, including but not limited to the preparation or submission of any FDA correspondence, or any similar correspondence in any foreign country regarding regulatory approval requirements for Viberzi®.

6. I have received a copy of the Stipulated Protective Order in this action. I have carefully read and understand its provisions.

7. I will comply with all provisions of the Protective Order, including but not limited to the following:

a. I will not disclose any information, documents, or things designated as Confidential information to anyone other than those persons specifically authorized by the Protective Order.

b. I will not use any Confidential information for any purpose other than the above-captioned case.

c. When requested to do so, I will return or destroy all materials containing Confidential information, and all documents and things that I have prepared relating thereto.

8. I will take reasonable steps to restrict access to any Confidential information to only those persons authorized by the Stipulated Protective Order to have such access. I will inform any of my employees or staff who encounter Confidential information of the terms of the Stipulated Protective Order and provide a copy to the employee.

9. I understand that my obligations regarding Confidential information under the Stipulated Protective Order apply equally to copies, summaries, excerpts, transcripts, indices, expert reports, or compilations of information containing Confidential information, as well as any knowledge or information derived from any such information I receive during this action.

10. I understand that if I violate the provisions of the Stipulated Protective Order, I will be subject to sanctions by the Court, and that the parties or third-parties that designated the information as Confidential information may assert other remedies against me.

11. I voluntarily submit to the jurisdiction of the U.S. District Court for the District of Delaware with respect to the enforcement of the Stipulated Protective Order, or with respect to any other order issued by the Court governing the use of confidential information.

12. I agree to appear in person before the U.S. District Court for the District of Delaware if there is any motion practice or hearing before the Court regarding my compliance with the Stipulated Protective Order.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Date: \_\_\_\_\_

\_\_\_\_\_

**EXHIBIT B**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ALLERGAN USA, INC., ALLERGAN	)	
HOLDINGS UNLIMITED COMPANY and	)	
EDEN BIODESIGN, LLC,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
AUROBINDO PHARMA LTD.,	)	
AUROBINDO PHARMA USA, INC.,	)	C.A. No. 1:19-cv-01727-RGA
ALKEM LABORATORIES LIMITED,	)	
HETERO LABS LIMITED, HETERO USA	)	
INC., MSN LABORATORIES PRIVATE	)	
LIMITED, MSN PHARMACEUTICALS,	)	
INC., SUN PHARMACEUTICAL	)	
INDUSTRIES LIMITED and ZYDUS	)	
PHARMACEUTICALS (USA) INC.,	)	
	)	
Defendants.	)	
	)	

**CERTIFICATION REGARDING PROTECTIVE ORDER**

1. I, \_\_\_\_\_, have been asked by counsel for Plaintiffs / Defendants [circle one] in the above-captioned matter to review certain confidential documents or other information that is subject to the Stipulated Protective Order that has been or will be entered by the District Court for the District of Delaware in the above-captioned case.

2. My present employer is \_\_\_\_\_ and my present work address is \_\_\_\_\_. My present job title/description is \_\_\_\_\_.

3. I have received a copy of the Stipulated Protective Order in this action. I have carefully read and understand its provisions.

4. I will comply with all provisions of the Protective Order, including but not limited to the following:

a. I will not disclose any information, documents, or things designated as Confidential information to anyone other than those persons specifically authorized by the Protective Order.

b. I will not use any Confidential information for any purpose other than the above-captioned case.

c. When requested to do so, I will return or destroy all materials containing Confidential information, and all documents and things that I have prepared relating thereto.

5. I will take reasonable steps to restrict access to any Confidential information to only those persons authorized by the Protective Order to have such access. I will inform any of my employees or staff who encounter Confidential information of the terms of the Protective Order and provide a copy to the employee.

6. I understand that my obligations regarding Confidential information under the Protective Order apply equally to copies, summaries, excerpts, transcripts, indices, expert reports, or compilations of information containing Confidential information, as well as any knowledge or information derived from any such information I receive during this action.

7. I understand that if I violate the provisions of the Protective Order, I will be subject to sanctions by the Court, and that the parties or third-parties that designated the information as Confidential information may assert other remedies against me.

8. I voluntarily submit to the jurisdiction of the United States District Court for the District of Delaware with respect to the enforcement of the Stipulated Protective Order, or with respect to any other order issued by the Court governing the use of confidential information.



I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Date: \_\_\_\_\_

\_\_\_\_\_

# EXHIBIT B

ORAL ORDER, Having reviewed the parties' submissions and heard oral argument relating to two disputes over the otherwise agreed-upon protective order (PO) in Civil Actions 18-192-CFC, 18-237-CFC, 18-247-CFC, and 18-275-CFC, IT IS HEREBY ORDERED that Defendants proposal with respect to paragraphs 19 and 20 of the contemplated PO, which would prohibit Plaintiffs from disclosing confidential information (CI) produced to Plaintiffs in discovery by any one Defendant to the outside counsel and experts of any other Defendant without first obtaining the producing Defendants consent, is REJECTED for the reasons stated by the Court and made clear by the Courts questioning of the parties at oral argument on October 17, 2018. The Court further notes that its decision was informed by the following: (1) this action is one of four actions that have been effectively consolidated for pre-trial purposes with a single schedule (including a consolidated Markman hearing) and common discovery; (2) Plaintiffs have proposed a reasonable alternative to Defendants' proposal that would limit the cross-disclosure of CI to Defendants' outside counsel and experts; (3) Defendants agree that their outside counsel are not competitive decision makers and are subject to an agreed-upon prosecution bar in the contemplated PO; (4) the deadline for the parties to identify their respective experts affords each Defendant sufficient time to seek Court intervention in the event a Defendant believes (i) an identified expert is a competitive decision maker or should be subject to the PO's prosecution bar, and/or (ii) good cause exists to prohibit the expert in question from having access to a Defendants CI; (5) Defendants' proposal would place an undue, unfair, and unnecessary burden on Plaintiffs; (6) Defendants' proposal would lead to significant disruptions in discovery, depositions, and court proceedings and would impose an undue burden on the Court; and (7) Defendants have not demonstrated that restrictions beyond Plaintiffs' proposed alternative are necessary to avoid the risk that a co-Defendant would use a producing Defendants' CI's to the competitive disadvantage of the producing Defendant. Ordered by Judge Colm F. Connolly on 10/18/2018. Associated Cases: 1:18-cv-00192-CFC, 1:18-cv-00237-CFC, 1:18-cv-00247-CFC, 1:18-cv-00275-CFC(nmf) (Entered: 10/18/2018)

As of October 19, 2018, PACER did not contain a publicly available document associated with this docket entry. The text of the docket entry is shown above.

*Pharmacyclics LLC et al v. Fresenius Kabi USA, LLC et al*  
1:18-cv-00192 (DED), 10/18/2018, docket entry

# EXHIBIT C

ORAL ORDER: Having reviewed the parties' submissions relating to disputes over the otherwise agreed-upon protective order ("PO"), IT IS HEREBY ORDERED that: (1) Defendants' proposal with respect to paragraph 13, which would preclude Plaintiffs (and presumably the Court, but not Defendants) from sharing any Defendant's confidential information ("CI") with anyone (including outside counsel and experts who are subject to the PO) associated with any other Defendant without the particular Defendant's prior consent, is REJECTED, as such an approach risks imposing an undue burden on the Court (independent of the burden it imposes on Plaintiffs) -- this decision is without prejudice to Defendants having an opportunity to propose a more targeted provision to address their concerns; (2) Lupin's request (paragraph 5(e)) to disclose CI to Ms. Naidu, a non-attorney whose activities have been recognized by courts to at least relate to competitive decisionmaking, is REJECTED; Lupin has an in-house attorney, to whom Plaintiffs do not object, and Lupin's staffing preferences do not outweigh the concerns raised by Plaintiffs about the sharing of their CI nor is it even clear that Ms. Naidu will be unable to manage the litigation without access to CI; and (3) Defendants' proposal (paragraphs 30-33) to permit clawback of inadvertently-produced irrelevant, non-privileged information is REJECTED, as Defendants' concerns are adequately protected by other provisions (e.g., regarding mistaken confidentiality designations) and the breadth of Defendants' proposal threatens to unreasonably burden the Court (in connection with, e.g., disputes regarding relevance). IT IS FURTHER ORDERED that the teleconference scheduled for tomorrow is CANCELLED. Ordered by Judge Leonard P. Stark on 9/13/2018. (etg) (Entered: 09/13/2018)

As of September 14, 2018, PACER did not contain a publicly available document associated with this docket entry. The text of the docket entry is shown above.

*H. Lundbeck A/S et al v. Apotex Inc. et al*  
1:18-cv-00088 (DED), 9/13/2018, docket entry 106

# EXHIBIT D

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

SHIRE, LLC,	)	14-CV-5694
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
COREPHARMA, LLC,	)	Camden, NJ
	)	May 18, 2015
Defendants.	)	11:01 a.m.
	)	
<hr/> SHIRE, LLC,	)	14-CV-6095
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
AMERIGEN PHARMACEUTICALS LIMITED,	)	
	)	
Defendants.	)	
	)	
<hr/> SHIRE, LLC,	)	15-CV-1454
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
PAR PHARMACEUTICALS, INC.,	)	
et al.,	)	
Defendants.	)	

TRANSCRIPT OF STATUS CONFERENCE  
BEFORE THE HONORABLE JOEL SCHNEIDER  
UNITED STATES MAGISTRATE JUDGE

APPEARANCES:

For the Plaintiffs:  
Shire, LLC

CYNTHIA S. BETZ, ESQUIRE  
MCCARTER & ENGLISH  
Four Gateway Center  
100 Mulberry Street  
Newark, NJ 07102

JEFFREY ELIKAN, ESQUIRE  
ERICA N. ANDERSON, ESQUIRE  
COVINGTON & BURLING, LLP  
One City Center  
850 Tenth Street NW  
Washington, DC 20001-4956

For the Defendants: MICHAEL INNES, ESQUIRE  
CorePharma, LLC BETH D. JACOB, ESQUIRE  
KELLEY, DRYE & WARREN, ESQUIRE  
101 Park Avenue  
New York, NEW YORK 10178

For the Defendants: SEAN R. KELLY, ESQUIRE  
Par Pharmaceuticals, SAIBER, SCHLESINGER, SATZ &  
Inc., et al., GOLDSTEIN, LLC  
18 Columbia Turnpike, Suite 200  
Florham Park, NJ 07932

STEPHEN YANG, ESQUIRE  
ARENT, FOX, LLP  
1717 K Street, NW  
Washington, DC 20006

For the Defendants: STEVEN GERBER, ESQUIRE  
Amerigen Pharmaceuticals GONZALEZ, SAGGIO & HARLAN, LLP  
Limited 155 Willowbrook Boulevard  
Suite 300  
Wayne, NJ 07470

KATHERINE E. ROHLF, ESQUIRE  
HUSCH, BLACKWELL  
120 South Riverside Plaza  
Suite 2200  
Chicago, IL 60606

Audio Operator: SARAH ECKERT

Transcribed by: DIANA DOMAN TRANSCRIBING, LLC  
P.O. Box 129  
Gibbsboro, New Jersey 08026-0129  
Office: (856) 435-7172  
Fax: (856) 435-7124  
Email: [dianadoman@comcast.net](mailto:dianadoman@comcast.net)

Proceedings recorded by electronic sound recording, transcript  
produced by transcription service.



1 responsive information that needs to be looked at by all  
2 defendants, we can do that, but by clearly sharing everything  
3 and forcing outside counsel to review more documents than it  
4 needs to, documents that is not necessary to review, Your  
5 Honor, this is -- this can be unworkable.

6 And another point made by Shire's counsel is the  
7 prejudice that it will suffer if there is a expert report by  
8 defendants where we have allegedly inconsistent positions.  
9 Well, Your Honor, if that's the case, Shire is free to ask the  
10 expert in a deposition the questions it wants to ask as long it  
11 does not disclose improperly the confidential information that  
12 belongs to other defendants. Shire is free to ask the  
13 defendants as long -- ask defendants experts as long as it does  
14 not use another defendant's experts opining a formulation that  
15 is completely different from another defendant's and try to use  
16 that as evidence against that other defendants. Your Honor,  
17 that, again, is improper, because the defendant whose evidence  
18 is going to be used, the other defendant does not have the  
19 opportunity to get discovery on that. He cannot go depose the  
20 witnesses of the other defendants. There's no discovery on it,  
21 and the evidence will be highly prejudicial, and that's why  
22 Your Honor needs to prevent such misuse and such cross use of  
23 each other's confidential information.

24 THE COURT: Thank you, counsel.

25 MR. YANG: Thank you.

1           THE COURT: Counsel, the Court is prepared to issue  
2           its ruling, and I'll confirm it in an order of the Court. The  
3           issue before the Court is whether the existing discovery  
4           confidentiality order that's in place between Shire,  
5           CorePharma, and Amerigen should be amended simply to include  
6           Par Pharma as an additional party to it or as Par Pharma  
7           suggests, paragraph 5 should be amended and a new paragraph 7  
8           should be added. The amendment to paragraph 5 would prevent  
9           the sharing of confidential information amongst the defendants.  
10          Par Pharma has listed in its May 6, 2015 letter brief, docket  
11          number 48, page 3, the bullet points, the information that  
12          would not be shared.

13               Shire opposes the amendments. It's not entirely  
14          clear what the positions of CorePharma and Amerigen are as to  
15          the entirety of the issues. As to paragraph 5, I think both  
16          defendants object to the proposed amendment.

17               For the reason to be discussed for the Court -- by  
18          the Court, the Court is going to deny Par's application, and  
19          the Court is going to issue an order including the docket  
20          number from the Par case in the existing discovery  
21          confidentiality order. The Court believes that existing  
22          paragraph 5 is necessary to assure the efficient case  
23          management of these three cases and the orderly administration  
24          and handling of the case. If the Court adopts Par's  
25          suggestion, the Court believes that it would create intractable

1 management problems dealing with depositions, expert reports,  
2 the Markman hearing, et cetera.

3 The Court has a lot of experience in these  
4 consolidated cases. This is the first time this issue has come  
5 up before this Court. In this Court's experience, it has not  
6 faced, and I hope it will continue to be the case, a problem  
7 with the sharing of confidential information between parties to  
8 a litigation.

9 The Court believes that paragraph 5 assures that no  
10 parties gain an unfair advantage and that it puts all parties  
11 on a level playing field. Frankly and candidly, the Court sees  
12 no material prejudice to Par from this ruling. Certainly, in  
13 every case, there's a risk of inadvertent disclosure, but  
14 again, as this Court has noted, in its experience, this has not  
15 been a problem. Paragraph 5 gives Par the protection it needs  
16 to assure that its information is not inadvertently disclosed  
17 and either intentionally or inadvertently misused for any  
18 purpose.

19 The Court wholeheartedly agrees with the suggestion  
20 made by CorePharma and Amerigen that if there are exceptional  
21 circumstances -- or exceptional might be too strong of a word.  
22 If there is good cause to limit the distribution of certain  
23 confidential information for a particular reason, there are  
24 provisions in the DCO where that can be accommodated, and  
25 certainly, this Court can entertain an application by any party

1 if it seeks to limit the distribution of its confidential  
2 information to a greater degree than is already set forth in  
3 paragraph 5 of the DCO.

4 Par has suggested that there's prejudice to the  
5 extent there be increased costs. The Court does not give that  
6 argument any material weight. The increased cost in the  
7 context of the costs of handling this type of litigation in the  
8 Court's view would be immaterial or certainly not significant  
9 enough to warrant the degree and prejudice reflected in the  
10 case law.

11 The Court does not believe the addition of paragraph  
12 7 is necessary. The Court is troubled by the fact that it  
13 would hamper plaintiff's ability to use relevant information  
14 against a defendant. I don't know how a Court can do that at  
15 this point in the case, but again, the Court has to emphasize  
16 that it has had a good deal of experience with these cases.  
17 The DCOs have gone smoothly. The Court hasn't experienced any  
18 problem witness this case. Granted, we're not that far along,  
19 but there seems to be no problems thus far with paragraph 5,  
20 and I would think that if paragraph 7 was significant and  
21 important enough for defendants in this type of litigation to  
22 have it included in a DCO, CorePharma and Amerigen would have  
23 raised it before Par raised it when it was brought into this  
24 litigation.

25 So for the reasons discussed, the Court is going to

1 deny Par's application. The Court is going to order that all  
2 parties shall be subject to the same DCO that's already entered  
3 in the case. All parties will be subject to the same terms  
4 that currently exist without prejudice to any party's right to  
5 move for good cause to prevent a dissemination of especially  
6 secret or sensitive information or information that one party  
7 believes for one reason or another is completely inappropriate  
8 to be distributed or produced to either a co-defendant or  
9 Shire.

10 So that's the Court's ruling on the DCO issue.

11 I should add, although I appreciate Par's offering to  
12 submit additional authority to the Court on this issue, the  
13 parties had a full and fair opportunity to brief the issue, and  
14 no authority has been submitted to the Court where the  
15 suggestions that Par proposed have been adopted by the Court.  
16 I don't doubt that there have been cases where similar orders  
17 have been entered, but for all the Court knows, that was done  
18 by consent, and if the parties consent to amended DCO, as per  
19 Par's suggestion, that's fine with the Court, but we don't have  
20 that issue here.

21 So now that we're done with the DCO issue, let's move  
22 to the discovery issues in the case. I have the parties'  
23 letter briefs, and what I'd like to do is what I do in every  
24 case, start with the plaintiff. We'll deal with the  
25 plaintiff's issues case by case, and then we'll get to each

# EXHIBIT E

1 IN THE UNITED STATES DISTRICT COURT

2 IN AND FOR THE DISTRICT OF DELAWARE

3 - - -

4 PHARMACYCLICS LLC and : CIVIL ACTION  
5 JANSSEN BIOTECH, INC., :

6 Plaintiff, :

7 vs. :

8 FRESENIUS KABI USA, LLC, et :  
9 al., :

10 Defendants. : NO. 18-192 (CFC)

11 PHARMACYCLICS LLC and : CIVIL ACTION  
12 JANSSEN BIOTECH, INC., :

13 Plaintiffs, :

14 vs. :

15 SHILPA MEDICARE LIMITED, et :  
16 al., :

17 Defendants. : NO. 18-237 (CFC)

18 - - -

19 Wilmington, Delaware  
20 Wednesday, October 17, 2018  
21 11:00 o'clock, a.m.

22 - - -

23 BEFORE: HONORABLE COLM F. CONNOLLY, U.S.D.C.J.

24 - - -

25 Valerie J. Gunning  
Official Court Reporter

1 PHARMACYCLICS LLC and : CIVIL ACTION  
2 JANSSEN BIOTECH, INC., :  
3 Plaintiffs, :  
4 vs. :  
5 Cipla Limited, et al., :  
6 Defendants. : NO. 18-247 (CFC)  
7 ----- :  
8 PHARMACYCLICS LLC and : CIVIL ACTION  
9 JANSSEN BIOTECH, INC., :  
10 Plaintiffs, :  
11 vs. :  
12 ZYDUS WORLDWIDE DMCC, et :  
13 al., :  
14 Defendants. : NO. 18-275 (CFC)  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

1 APPEARANCES (Continued):  
2  
3 SCHIFF HARDIN LLP  
4 BY: JOHN K. HSU, ESQ.  
(Washington, D.C.)  
5  
6 Counsel for Defendants  
7 Fresenius Kabi USA, LLC and Fresenius Kabi  
8 Oncology Limited  
9  
10 SMITH, KATZENSTEIN & JENKINS LLP  
11 BY: EVE H. ORMEROD, ESQ.  
12  
13 Counsel for Defendant  
14 Shilpa Medicare Limited  
15  
16 RICHARDS, LAYTON & FINGER, PA  
17 BY: KELLY E. FARNAN, ESQ.  
18  
19 Counsel for Defendants  
20 Sun Pharma Global FZE and  
21 Sun Pharmaceutical Industries Ltd.  
22  
23 POTTER, ANDERSON & CORROON LLP  
24 BY: DAVID E. MOORE, ESQ.  
25  
-and-  
21  
22 KASOWITZ BENSON TORRES LLP  
23 BY: HERSHY STERN, ESQ.  
(New York, New York)  
24  
25 Counsel for Defendants  
Zydus Worldwide DMCC and Cadila Healthcare  
Limited

3  
1 APPEARANCES:  
2  
3 MORRIS, NICHOLS, ARSHT & TUNNELL LLP  
4 BY: JEREMY A. TIGAN, ESQ.  
5  
6 -and-  
7  
8 COVINGTON & BURLING LLP  
9 BY: ERICA N. ANDERSEN, ESQ. and  
10 CHANSON CHANG, ESQ. ESQ.  
11 (Washington, D.C.)  
12  
13 -and-  
14  
15 PATTERSON BELKNAP.  
16 BY: LACHLAN S. CAMPBELL-VERDUYN, ESQ.  
17 (New York, New York)  
18  
19 Counsel for Plaintiff  
20 Pharmacyclics LLC  
21  
22 FARNAN LLP.  
23 BY: BRIAN E. FARNAN, ESQ.  
24  
25 -and-  
19  
20 SCHIFF HARDIN LLP  
21 BY: THOMAS RAMMER, ESQ.  
(Chicago, Illinois)  
22  
23 -and-  
24  
25

5  
1 APPEARANCES (Continued):  
2  
3 HEYMAN ENERIO GATTUSO & HIRZEL LLP  
4 BY: DOMINICK T. GATTUSO, ESQ.  
5  
6 -and-  
7  
8 ALSTON & BIRD LLP  
9 BY: NATALIE C. CLAYTON, ESQ.  
10 (New York, New York)  
11  
12 Counsel for Defendants  
13 Sandoz Inc. and Lek Pharmaceuticals d.d.  
14  
15 SHAW KELLER LLP  
16 BY: KAREN E. KELLER, ESQ.  
17  
18 -and-  
19  
20 POLSINELLI PC  
21 BY: MARK T. DEMING, ESQ. and  
22 HELENA BEREZOWSKYJ, ESQ.  
(Chicago, Illinois)  
23  
24 Counsel for Defendant  
25 Teva Pharmaceuticals USA, Inc.  
20  
21 PHILLIPS GOLDMAN McLAUGHLIN & HALL, P.A.  
22 BY: JOHN C. PHILLIPS, ESQ.  
23  
24 -and-  
25



1 single you out. It's just because my guess is you read 7.1.  
 2 You say, well, my procedure is the same thing as 7.1 and  
 3 it's pretty close, but it's actually a little bit different.  
 4 I add the second prong explicitly.

5 MR. GATTUSO: Understood, Your Honor.

6 THE COURT: Thanks very much.

7 And, incidentally, for what it's worth, Mr.

8 Gattuso, we've already had disputes where there was no  
 9 averment. All right.

10 So let's see. Who is going to argue? Are you  
 11 going to have multiple arguers for the defendant? Are both  
 12 Mr. Deming and Mr. Bernstein arguing?

13 MR. DEMING: That's right, Your Honor. I will  
 14 be presenting on the cross disclosure question and  
 15 Mr. Bernstein will be presenting on the Cipla issue.

16 THE COURT: Okay. Go ahead then.

17 MR. DEMING: Thank you, Your Honor.

18 So, Your Honor, the issue that I will be  
 19 presenting on here is the treatment of defendants'  
 20 confidential information by plaintiffs and what they are  
 21 permitted to do with it and who they are permitted to  
 22 disclose it to.

23 The parties, as Mr. Gattuso said, had several  
 24 meet and confers about this and tried to reach agreement,  
 25 and both sides made reasonable efforts to come together in

1 their briefs, their Markman briefs or their dispositive  
 2 motions. You know, these are going to be core documents  
 3 that the parties are going to have to deal with  
 4 collectively.

5 I know there's additional comments in the letter  
 6 about, you know, the procedure at hearings and at trial, and  
 7 defendants are not suggesting that we're going to need to  
 8 have some kind of procedure where we're going to have people  
 9 shuffling in and out of the courtroom. I think the  
 10 expectation is we're going have to all sit down and come up  
 11 with something that makes sense so that everyone can  
 12 participate in those hearings.

13 Defendants' concern --

14 THE COURT: Let me ask you, if you can't agree,  
 15 I guess you have to involve me?

16 MR. DEMING: Well, Your Honor, I guess if the  
 17 parties can't agree, then we would have to present, you  
 18 know, competing proposals to the Court, but it would be our  
 19 expectation and our hope that we could agree.

20 THE COURT: So would you at least agree that  
 21 this will create at least potentially administrative burdens  
 22 on the Court?

23 MR. DEMING: Well, Your Honor, I think any time  
 24 there's an order in the case, a protective order that  
 25 requires the parties to interpret it and if they can't come

1 the middle, but at the end of the day, we have somewhat  
 2 fundamental different approaches to how this should  
 3 proceed.

4 Defendants' proposal is a reasonable attempt at  
 5 compromise. It's practical. What we had proposed is that  
 6 plaintiffs can cross disclose one defendants' information to  
 7 another defendant when they file a document with the Court,  
 8 and that the Court, when it's issuing any kind of orders or  
 9 memorandum opinions, does not need to worry about, you know,  
 10 who can this ordering to. It can simply provide that it  
 11 will be served on all outside counsel, and that that extent  
 12 of cross disclosure, while it is some sharing of defendants'  
 13 confidential information among them, it's at least limited,  
 14 and therefore reduces the risk of inadvertent disclosure and  
 15 prejudice.

16 THE COURT: So actually how does it reduce it  
 17 since they get to disclose it in time?

18 MR. DEMING: Your Honor, they're only disclosing  
 19 what would be the most important documents.

20 THE COURT: So it's the most important stuff the  
 21 risk still exists for as opposed to the less important  
 22 stuff?

23 MR. DEMING: Your Honor, it's the most important  
 24 documents to their arguments, and so the difference to  
 25 illustrate, Your Honor, is that they're citing something in

1 to an agreement as to how it's supposed to be interpreted,  
 2 there's always the potential for a dispute to arise. Even  
 3 with a clear order, you know, typically, the orders are  
 4 without prejudice to a party seeking leave to amend it. And  
 5 so even with an order in place, it's possible that something  
 6 could come up where a party would be potentially in court  
 7 for some kind of relief.

8 So I don't think there's any way to just resolve  
 9 this, you know, where there is zero chance that anything  
 10 will ever come up again. But I think all involved, we  
 11 certainly don't try and take up the Court's time  
 12 unnecessarily, and we'll do our best to avoid any kind of  
 13 disputes.

14 Going back to the difference between the kind of  
 15 disclosure that we're suggesting would be acceptable to us,  
 16 again, as a compromise, we're trying to reach halfway there.  
 17 Plaintiffs are proposing to be able to use defendants'  
 18 information kind of anywhere and so it could be in discovery  
 19 responses, in contentions, in expert reports, and the kinds  
 20 of documents where they will be unilaterally determining  
 21 anything that they deem to be remotely relevant to a  
 22 particular question and then producing it to our  
 23 co-defendants.

24 And --

25 THE COURT: You would agree that under their

1 proposal, those disclosures would still be limited to  
 2 outside counsel and experts?  
 3 MR. DEMING: That's right, Your Honor. That's  
 4 what we propose, just to outside counsel and experts. But I  
 5 think it's an important distinction, because there's going  
 6 to be broader disclosures. I think just necessarily so,  
 7 they're going to be disclosing more in those types of papers  
 8 than they would in a court filing.

9 And the other issue that comes up is Court  
 10 Orders or Court filings will be served on all parties, and  
 11 so if Teva information is used in a Markman brief, we'll be  
 12 aware of it and we'll understand who it has gone to, and in  
 13 that sense we'll have some control over where the document  
 14 has gone.

15 If they serve a discovery response on another  
 16 party in which they include Teva information but didn't  
 17 serve us with that document, let's say it's a discovery  
 18 request that we didn't make, we would actually have no way  
 19 of even knowing that the information had been disclosed to  
 20 another party, and so that's where we lose all control over  
 21 our proprietary, you know, very sensitive information.

22 And frankly, Your Honor, you know, we don't see  
 23 the need for plaintiffs to be using our information against  
 24 other defendants. You know, as we mentioned in the letter,  
 25 the question of infringement is going to be defendant

1 or that, you know, that their formulation has these  
 2 ingredients or doesn't have these ingredients, because there  
 3 could be a risk for competitive harm there as far as who is  
 4 going to obtain approval, who is going to obtain approval  
 5 first, and who may be able to enter the market before the  
 6 other defendants. And so that's why, you know, we believe  
 7 the defendants are in the best position to evaluate when  
 8 it's okay to share that kind of information among each  
 9 other, but it's not the kind of determination that  
 10 plaintiffs should be making.

11 THE COURT: Who is your client?

12 MR. DEMING: Teva Pharmaceuticals, Your Honor.

13 THE COURT: Are they a competitor, direct  
 14 competitor of the plaintiff?

15 MR. DEMING: On this particular product, I would  
 16 say they could be, Your Honor, if their drug application was  
 17 approved and they entered the market.

18 THE COURT: And under the plaintiffs' proposal,  
 19 do you get to see the confidential information of  
 20 plaintiffs?

21 MR. DEMING: It's true, Your Honor, that  
 22 opposing counsel as in any case, you know, there's sensitive  
 23 information. That's why we have protective orders. And so,  
 24 you know, we will have their information and they will have  
 25 our information, and there is some competitive concern

1 specific, so, you know, anything about Teva's formulation is  
 2 not going to be relevant to what another --

3 THE COURT: Sorry. I'm sorry. Just focusing on  
 4 that last argument you made, does anything prevent you from  
 5 sharing discovery requests that were served on you with a  
 6 co-defendant?

7 MR. DEMING: Serving discovery requests?

8 THE COURT: In other words, you said you could  
 9 not follow it. In other words, if the plaintiffs served on  
 10 Defendant A some request, you would lose control over it.  
 11 You wouldn't know who got it. Couldn't you have an  
 12 agreement with the other defendants that they share the  
 13 discovery requests with you?

14 MR. DEMING: I suppose, Your Honor, that could  
 15 be arranged. I don't know. You know, in this case there  
 16 are multiple types of patents. This isn't the kind of case  
 17 where all the patents are related to the same thing, and so  
 18 here we've got patents that go to particular types of  
 19 formulations, patents that go to particular types of forms  
 20 of the active ingredient. And so among the defendants, they  
 21 may have different formulations. They may be using  
 22 different forms of the active ingredient.

23 And so there may be circumstances where one  
 24 defendant would not necessarily want another defendant to  
 25 know that they are serving that particular discovery request

1 there.

2 THE COURT: So do I have to be worried about you  
 3 inadvertently disclosing confidential information that  
 4 plaintiffs give you?

5 MR. DEMING: I certainly hope not, Your Honor.  
 6 I always do my best to abide by protective orders and take  
 7 all of the appropriate precautions.

8 THE COURT: And I take comfort in that. Why  
 9 can't I take the same comfort in that restriction being  
 10 equal on the plaintiffs?

11 MR. DEMING: Your Honor, I think the goal is to  
 12 limit -- it's always an inadvertent disclosure.

13 THE COURT: I asked you about inadvertent  
 14 disclosures.

15 MR. DEMING: Yes.

16 THE COURT: You've given me some comfort you're  
 17 going to comply with the protective order. Why can't I take  
 18 the same comfort when it comes to plaintiffs' outside  
 19 counsel?

20 MR. DEMING: Well, that's what I'm trying to go  
 21 through, Your Honor. If there is a fraction of a percentage  
 22 chance that one party could have an inadvertent disclosure,  
 23 if we multiply that by, I think there's seven or eight  
 24 parties, defendants in this case, it just exponentially  
 25 increases the chances that this could happen.

1 THE COURT: Wait. You didn't do the math. How  
2 does it exponentially increase?

3 MR. DEMING: Your Honor --

4 THE COURT: I mean, it might increase, assuming  
5 there's an assumption, how many defendants are?

6 MR. DEMING: Eight.

7 THE COURT: I guess eight. You just said a  
8 fraction. So fraction .001 times eight is still miniscule.  
9 I mean, I am really stuck at why you should be treated  
10 differently than the plaintiffs' outside counsel and  
11 experts.

12 Are you a competitive decision-maker?

13 MR. DEMING: No, Your Honor.

14 THE COURT: So would you agree then that the  
15 outside counsel and the outside experts, you would agree  
16 that they're not competitive decision-makers?

17 MR. DEMING: I don't know who plaintiffs'  
18 experts are. I don't think they disclosed those to us  
19 yet.

20 THE COURT: I will tell you what. Clearly, if  
21 they were a competitive decision-maker, you would be free to  
22 make an application at that point. Right?

23 MR. DEMING: Well, we would object presumably,  
24 Your Honor. I think that raises a good point in that  
25 plaintiffs want to, want permission to disclose defendants'

1 it was a "shall" provision. That defendants shall in good  
2 faith entertain a reasonable request for limited cross  
3 disclosure, so that if there is in any kind of situation  
4 where it would be appropriate for there to be product  
5 disclosure, that we'll consider it in good faith and agree  
6 to it if it's appropriate. And, again, you know, where it's  
7 not our intent to have serial disputes and come in front of  
8 the Court on things where, you know, we don't have  
9 legitimate concerns.

10 May I just consult my notes for a minute, Your  
11 Honor?

12 So, again, I think there is -- there is risk.  
13 Now, you know, whether the risk is a fraction of a percent  
14 or five percent, you know, reasonable minds can disagree,  
15 but there is risk of serious competitive harm, I think more  
16 so in this case than in other cases because we're not all  
17 sued on all the same patents.

18 I believe there are over a dozen patents that  
19 plaintiffs had asserted in the case, but for some of the  
20 defendants, there's only two or three at issue.

21 THE COURT: Why does the risk of inadvertent  
22 disclosure correlate with the number of patents?

23 MR. DEMING: Your Honor, in other cases where  
24 all of the formulations may be identical or very nearly  
25 identical, so in certain types of drug product cases, like

1 information to other defendants' experts, and so under the  
2 protective order, in most cases plaintiffs disclose their  
3 experts to defendants, defendants determine if they have an  
4 objection and make them if appropriate, but we don't  
5 evaluate each other's experts.

6 But in this case --

7 THE COURT: But you would agree to.

8 MR. DEMING: We could, Your Honor. That would  
9 put some potential strain on defendants, you know, trying to  
10 have a common focus on the invalidity questions in this  
11 case. You know, I think it would be more appropriate for  
12 Teva's experts to only see Teva's information and  
13 plaintiffs' information, and for whatever other defendants'  
14 experts to be limited to their information. And, again,  
15 defendants aren't objecting to plaintiffs' outside counsel  
16 having access to all defendants' information. That's  
17 necessarily going to be the case. So plaintiffs aren't  
18 being deprived of anything. They have access to everything.

19 The only question here is really a matter of  
20 convenience. You know, can they serve one document on Teva  
21 and everyone else, or can they serve five or four, whatever  
22 one might be appropriate. And that goes back to the  
23 clarification I made at the beginning of the hearing, Your  
24 Honor in that we're trying to be practical, we're trying to  
25 be reasonable, and we tried to include that provision that

1 an ophthalmic eyedrop, it's very unlikely there's going to  
2 be any kind of variations in the formulations, so there's  
3 less of a risk of defendants', you know, formulation and  
4 sensitive information being disclosed because odds are all  
5 the formulations are the same anyway.

6 What we see here based on how the patents  
7 are asserted against different defendants, presumably,  
8 there's differences in the defendants' formulations, ones  
9 that are significant enough that it has affected what  
10 patents the plaintiffs chose to a certain against those  
11 defendants.

12 THE COURT: So I'm still having a hard time.  
13 You're doing a good job. I'm sorry. I'm trying to figure  
14 out why the risk increases based on the number of patents or  
15 the amount of information that's disclosed to the other  
16 side.

17 MR. DEMING: Your Honor, I may have misspoken.  
18 It's not just that there's more patents. It's that the  
19 specific patents that are asserted against each defendant  
20 are different.

21 THE COURT: But even that, and just help me  
22 out. It's not a gotcha question. I'm trying to understand  
23 it. Why would that increase the risk of inadvertent  
24 disclosure?

25 MR. DEMING: Because there may be meaningful

1 differences between the defendants' formulations, for  
2 example, and that if that information was disclosed  
3 inadvertently, it would have a very tangible injury.

4 THE COURT: But the disclosures being made are  
5 going to outside counsel and experts. So why does the risk  
6 increase? I may get you on why as to potential prejudice.  
7 Why does the risk increase?

8 MR. DEMING: I wasn't speaking to the risk of  
9 disclosures. The risk that would lead to an injury. In  
10 other cases if there's not meaningful differences between  
11 the formulations, the risk can be the same in both cases,  
12 but if the differences are insubstantial, then if that, if  
13 that happens, you know --

14 THE COURT: It's not the risk of  
15 disclosure. The risk of prejudice.

16 MR. DEMING: That's right, Your Honor.

17 THE COURT: All right.

18 MR. DEMING: What we're urging the Court to  
19 consider is the risk of that prejudice against plaintiffs'  
20 stated need for these documents, and, again, as far as  
21 infringement is concerned, there is no need. The only  
22 documents that matter for whether or not Teva infringes  
23 these patents is Teva's documents, and Teva's documents  
24 don't matter for other defendants and vice-versa.

25 The only thing that plaintiffs identified in

1 very high.

2 I don't mean to go on. I will wrap up my  
3 comments. My final thought is that these types of  
4 provisions in protective orders are very common, and I would  
5 say it's the norm in most cases to have protections like  
6 what defendants are advocating for as opposed to what  
7 plaintiffs are seeking. You know, usually, it's not -- it's  
8 just not disputed, but when it has been disputed, I think  
9 that the courts tend to go the way that the defendants are  
10 urging in this case. We've cited a couple of cases in our  
11 letter in the footnote.

12 And I also wanted to make Your Honor aware that  
13 even, I think it was yesterday, a similar dispute was before  
14 Judge Stark, and the defendants were urging a provision that  
15 had two components. One component said, no cross  
16 disclosure, and the second component got into the  
17 admissibility question and Judge Stark said, I'm not going  
18 to address the admissibility question right now, but I will  
19 grant the defendants the relief they were requesting as far  
20 as no cross disclosure. And I think that that is how, you  
21 know, the Court generally tends to handle this dispute.

22 THE COURT: Let me ask you about that then  
23 because somebody cited a recent court order from Judge  
24 Stark, which I read, persuasive, on September 13th of this  
25 year.

1 their letter were issues of secondary considerations, things  
2 like commercial success and long-felt need, but frankly,  
3 Your Honor, plaintiffs are just identifying something that's  
4 part of any patent case. They are not identifying any kind  
5 of particular concern.

6 It's all very hypothetical and speculative right  
7 now. You know, if there are materials -- and I'm not even  
8 agreeing that it would be appropriate for one defendant's  
9 information to be used against another defendant on the  
10 issue of secondary considerations.

11 THE COURT: You did agree that would be an  
12 evidentiary issue.

13 MR. DEMING: And that's a bridge that we can  
14 cross when we get there Your Honor. And we're not proposing  
15 in our order this be some sort of blanket ruling on  
16 admissibility. All we're proposing is that if something  
17 like that comes up, plaintiffs should reach out to us again  
18 with the provision that we intended to include there,  
19 paragraph 18 or 19. They can reach out to us and we can  
20 talk about whether or not we would agree to limited cross  
21 disclosure for that purpose at that time, and then we'll  
22 have something concrete to discuss. We're not talking  
23 hypotheticals.

24 And so that is where we think the need is very  
25 low, Your Honor, versus the prejudice to plaintiff being

1 MR. DEMING: That's right. Sorry. I didn't  
2 mean to interrupt you.

3 THE COURT: No, that's all right. And so he at  
4 least obviously was thinking about the issue and went  
5 against your position today.

6 MR. DEMING: I don't agree with that  
7 interpretation, Your Honor. And that is based on the  
8 quotation that plaintiffs included in their letter, they're  
9 the ones that cited this September 13th order.

10 I've got the old minute entry order here, and I  
11 can --

12 THE COURT: I'm looking at it.

13 MR. DEMING: Okay.

14 THE COURT: Go ahead.

15 MR. DEMING: In fact, it's about, after Judge  
16 Stark says that the proposal without the particular  
17 defendant's prior consent is rejected, and he continues.  
18 This decision is without prejudice to defendants having an  
19 opportunity to propose a more targeted provision to address  
20 their concerns. And so he was not in my interpretation of  
21 this minute entry order rejecting the concern out of hand.  
22 The proposal in that case was much broader than the  
23 defendants'.

24 The defendants didn't make the kind of attempt  
25 at meeting halfway that we made in this case. And, in fact,

1 we were aware of this decision when we were meeting and  
 2 conferring with plaintiffs, and we crafted our proposal  
 3 that's in our protective order, with this in mind, that  
 4 we're trying to relief the burden on the Court. We're  
 5 trying to simplify some of the logistics that plaintiffs are  
 6 going to have to deal with when they're filing things with  
 7 the Court or attending arguments, but then taking to mind  
 8 still that Judge Stark acknowledged that there should be  
 9 something more reasonably favored that would be acceptable,  
 10 and that's what we tried to propose.

11 THE COURT: Well, you mentioned the decisions.  
 12 I mean, the decisions that are in your letter that  
 13 address -- I don't know enough to know what the norm is. I  
 14 mean, it's not the norm in my experience, although I'm not  
 15 going to say that I have such a broad range of experience  
 16 that I'm in a position to know. But it's not the norm that  
 17 I've seen.

18 So the cases you cite, I mean, you've got a New  
 19 Jersey case. But the Delaware cases you cite, I mean, there  
 20 are two cases, but they're stipulated orders, so basically  
 21 the sides agreed to the provision.

22 MR. DEMING: Your Honor, I believe that the  
 23 first two cases, the New Jersey case and the Astellas versus  
 24 Actavis Delaware case, those were disputed cases where the  
 25 Court resolved the dispute in defendant's favor.

1 THE COURT: So the Astellas case, that's the  
 2 Burke case, right, Magistrate Judge Burke?

3 MR. DEMING: Your Honor, unfortunately --

4 MR. GATTUSO: Your Honor, it is.

5 THE COURT: Thank you. I mean, you know, it's a  
 6 one-sentence, the one-sentence document. But go ahead.

7 I guess the problem here is you cited some  
 8 things, they cited some things, and, frankly, the thing I  
 9 found most persuasive in terms of authority was the oral  
 10 order from Judge Stark. I understand you're distinguishing  
 11 it because certainly, he granted leave to come forward with  
 12 a more targeted agreement.

13 MR. DEMING: You're right, Your Honor. The  
 14 order I was referring to, a teleconference just yesterday,  
 15 was also a Judge Stark case, and so defendants would be  
 16 happy to submit the transcript of that hearing as soon as  
 17 it's available.

18 THE COURT: That's okay. I appreciate the  
 19 offer, but that's not --

20 MR. DEMING: Sure. I think it illustrates that  
 21 Judge Stark, you know, he was distinguishing even between  
 22 those two cases, and the type of provision that was before  
 23 him yesterday is very much, it's almost verbatim to what  
 24 we're proposing in our case. And he then granted the  
 25 defendant's relief in that second case.

1 THE COURT: All right. Thanks.

2 MR. DEMING: All right. Thank you, Your Honor.

3 MS. CLAYTON: Your Honor, can I make one point?

4 THE COURT: Can you identify yourself?

5 MS. CLAYTON: Yes. Natalie Clayton for Sandoz.

6 You asked whether our provision would be more  
 7 confusing for the Court. In my experience, not having this  
 8 provision actually leads to more disputes during the expert  
 9 discovery phase. We have previously been in cases where  
 10 there was not a provision that prohibited cross disclosure,  
 11 and we received infringement expert reports from plaintiffs  
 12 that contained documents from other defendants that we had  
 13 never seen before, had never had access to before, and  
 14 therefore had no way to either investigate or corroborate  
 15 what was in those documents. And my fear here is that is  
 16 exactly what plaintiffs intend to do here, serve expert  
 17 reports where we are seeing documents from other defendants  
 18 for the first time.

19 If I got a request from the other defendants to  
 20 have access to more Sandoz documents to try to see the  
 21 context, my guess is my client wouldn't allow me to provide  
 22 those documents because they are highly sensitive.

23 So we face the risk of severe prejudice here of  
 24 getting expert reports with evidence that we have no way to  
 25 look at beforehand and no way to challenge. And, in

1 addition, in cases where there has happened, it resulted in  
 2 motions to strike the expert reports, the expert discovery  
 3 period being extended protractedly. And so I have seen this  
 4 provision when it's not there to actually cause significant  
 5 issues with the Court and the schedule of the case.

6 THE COURT: Do you mind coming up to the podium  
 7 to follow up on this?

8 MS. CLAYTON: Sure.

9 THE COURT: So I'm trying to understand. My  
 10 initial reaction when I hear this is it just seems very  
 11 unfair that a defendant during expert, during the expert  
 12 phase of the case would be confronted with an expert report  
 13 that relies on documents from a competitor that were so  
 14 highly sensitive that you didn't have access to them in the  
 15 ordinary course.

16 MS. CLAYTON: Right.

17 THE COURT: So why don't I just address that? I  
 18 mean, and maybe help me understand.

19 What kind of documents and what were they? What  
 20 did they address? And why did the Judge let them in? My  
 21 initial reaction is that doesn't strike me as fair to begin  
 22 with, but maybe I'm missing something.

23 MS. CLAYTON: Right. So to address the  
 24 questions in reverse, ultimately, they withdrew that expert  
 25 report and served a new one, but it was after a lot of back

1 and forth with the parties and the Court and not disrupting  
2 the schedule. And in that case, they were actually  
3 polymorph patents that were at issue, which are similar to  
4 the patents at issue here. And what we received were expert  
5 reports that not only cited my client's information from  
6 their ANDA, but information from another defendant'S ANDA  
7 that we had never seen before, and we couldn't even share  
8 with our expert because he didn't have permission from the  
9 other defendant to see their documents.

10 And so it created a massive procedural and  
11 logistical firestorm in the case, and that is really  
12 Sandoz's main concern here, is that we're going to get the  
13 expert discovery, we're going to face the same issues like  
14 that, and it's going to unnecessarily delay expert discovery  
15 and delay the case whereas if they have to come to us on a  
16 document-by-document basis and say, you know, Sandoz, you  
17 have the document that says how great it is. We think we  
18 should be able to use that against all defendants for  
19 commercial success. That is a reasonable discussion for the  
20 parties to entertain. But what's not reasonable is for us  
21 to be blindsided by documents that are about another party's  
22 product that we've never seen before and then try to  
23 scramble to figure out how are we going to deal with this in  
24 the middle of expert discovery.

25 THE COURT: All right.

1 use, and I think fairly so, because this is an evidentiary  
2 issue.

3 I heard Mr. Deming say --

4 THE COURT: Wait. Do you have anything else to  
5 add on that point?

6 MS. ANDERSEN: Relatedly, Mr. Deming said that  
7 it was speculative, that we would need to use these  
8 documents, for example, for validity, defendants' documents.  
9 It's actually not speculative.

10 So defendants have already served a common  
11 interrogatory on plaintiffs, one common interrogatory  
12 dealing with all of plaintiffs' validity theories for all of  
13 the patents.

14 We heard Mr. Deming say the fact that there were  
15 different patents is meaningful here, but they served us one  
16 single interrogatory. Defendants get the benefit of that  
17 for validity.

18 And they have said that substantively though if  
19 you get a document that says Imbruvica is a real commercial  
20 success, or the reason that we are pursuing this product is  
21 because it's a major advance in cancer treatment, we're not  
22 allowed to use that.

23 So what Mr. Deming is talking about is far from  
24 speculative. It's something that has already come up  
25 because they've asked us common discovery in this case.

1 MS. CLAYTON: Thank you, Your Honor.

2 THE COURT: Thank you.

3 MS. ANDERSEN: Good morning, Your Honor. Erica  
4 Anderson for the plaintiffs.

5 I want to address Ms. Clayton's point first,  
6 which is that defendants' proposal as currently written  
7 doesn't actually preclude what Ms. Clayton is talking about.  
8 So the proposal as of now says we can use documents in  
9 filings, and that could involve the use that Ms. Clayton was  
10 talking about. It also doesn't prohibit our use of one  
11 defendant's information against another. It just says you  
12 can't disclose it.

13 So, for example, in expert reports, we could  
14 prepare a bunch of redacted copies. That's how we  
15 understand defendant's provision as it's currently written.  
16 That doesn't take care of this evidentiary issue. They've  
17 just said, you can't disclose one defendant's information to  
18 another. It doesn't say you may not use it, I think  
19 properly, because that's an evidentiary question. So it's  
20 actually our proposal which allows for circulation of this  
21 information between outside counsel that gives defendants  
22 notice of all of the theories in the case.

23 Defendants' proposal as currently written puts  
24 administrative hurdles up to plaintiffs using the  
25 information, but the protective order doesn't preclude that

1 And, you know, to their point that they would be in the  
2 dark, we are happy. I mean, these cases are effectively  
3 consolidated up until trial, and I know that the parties are  
4 supposed to talk about trial and how it's to proceed, but we  
5 only have one trial date as well. We're happy to serve all  
6 discovery responses, all expert reports, all discovery on  
7 all parties because we think in a consolidated case like  
8 this, that makes the most sense. And defendants are not in  
9 the dark as to plaintiffs' theories and plaintiffs are able  
10 to substantively address issues.

11 THE COURT: Okay. Anything else on that  
12 particular point?

13 MS. ANDERSEN: I think -- no, Your Honor.

14 THE COURT: Then can I ask -- can you switch?

15 MS. ANDERSEN: Sure.

16 THE COURT: Ms. Clayton, is it?

17 MS. CLAYTON: Yes, Your Honor.

18 THE COURT: Can you tell me why I shouldn't be  
19 persuaded by Ms. Andersen's point?

20 MS. CLAYTON: Which particular point, Your  
21 Honor?

22 THE COURT: Well, her entire thing. If the  
23 concern is you're going to get blindsided, she has pointed  
24 out under the plaintiffs' proposal, you'll have access to it  
25 during the ordinary course of discovery so you won't be



1 blindsided.

2 MS. CLAYTON: Well, we won't be blindsided once  
3 we receive it, but we're not going to have any ability to  
4 access at a broader level any of the other defendants'  
5 documents that they've cited against us.

6 So, for example, they might be citing a document  
7 that they're entirely taking out of context. You know,  
8 let's say they cite a Teva document for infringement  
9 purposes against Sandoz. Right. But we could try to go  
10 to Teva and say, well, we want broader access to your ANDA  
11 to understand the context of this. The reality is, I would  
12 be shocked if Teva gave us that access, because that would  
13 be exposing even more of their confidential information  
14 to us.

15 So while we might be apprised of the arguments,  
16 we are prejudiced in that we're not going to be able to  
17 fully respond if they're able to choose to use which  
18 documents they can't use against us, and, you know, without  
19 us having the same opportunity to access the documents of  
20 the defendants, which the defendants just -- you know, I've  
21 never seen defendants come to agreement that, you know, all  
22 defendants can have access to all of the defendants'  
23 production in the case just because there is such, you know,  
24 highly information in the documents.

25 THE COURT: Have you done a lot of ANDA cases?

1 THE COURT: And when was that case?

2 MS. CLAYTON: That case wrapped up two years  
3 ago, so --

4 THE COURT: Who was the judge?

5 MS. CLAYTON: Judge Crotty.

6 THE COURT: Ms. Anderson?

7 MS. ANDERSEN: If I could respond to that  
8 briefly.

9 I have also been involved in a number of ANDA  
10 cases at this point, and it has been a mixture of protective  
11 orders like defendants are proposing and the one the  
12 plaintiffs are proposing here. But what I can say --

13 THE COURT: Have you ever litigated the issue?

14 MS. ANDERSEN: I have litigated the issue. Your  
15 Honor, it's actually the Shire case that we cited in our  
16 letter brief. We litigated. And in that case, some of the  
17 defendants wanted cross disclosure for the exact reason I'm  
18 saying, is that they want to know all the theories. They  
19 want to know if they're being inconsistent, and we think  
20 plaintiffs' provision does that and some of the defendants  
21 did not.

22 And there we were asking for a very similar  
23 provision, and Magistrate Judge Schneider in the District of  
24 New York went along with our provision. So we have  
25 litigated it. We have agreed --

1 MS. CLAYTON: I have, Your Honor.

2 THE COURT: Have you ever been in a case where a  
3 protective order was consistent with what plaintiffs are  
4 asking for?

5 MS. CLAYTON: I can't say -- sitting here, I  
6 can't say I can tell you whether -- I don't recall one that  
7 does this.

8 The majority of the cases I've been in, cross  
9 disclosure has not been permitted. In the one case where it  
10 was permitted is the case that I was referencing where it  
11 caused a huge issue.

12 THE COURT: At least one case you've been in  
13 where cross disclosure was permitted?

14 MS. CLAYTON: Yes, Your Honor.

15 THE COURT: But you can't think of any others?  
16 Just one?

17 MS. CLAYTON: That's the only one that comes to  
18 mind.

19 Again, I've been in a lot, so I can't say one  
20 way or the other how many there might have been, but in  
21 practice, historically, the norm has been the defendants'  
22 position.

23 THE COURT: What Court was the --

24 MS. CLAYTON: Southern District of New York was  
25 that one.

1 THE COURT: Have you ever lost it?

2 MS. ANDERSEN: I have not, Your Honor. And I  
3 also want to say that even though we've started out in many  
4 cases doing this type of discovery even in consolidated  
5 cases, what I can tell Your Honor is at some point during  
6 litigation, it almost always breaks down where we have to  
7 have some global agreement. Now, whether that's the Markman  
8 hearing, that's what we referenced in our letter, or it's  
9 expert discovery, because defendants are using a common  
10 expert, or it's written discovery because they're  
11 propounding common interrogatories. It's varied. Sometimes  
12 we've gotten up to the pretrial order and then said, okay.  
13 What are we going to do about this?

14 THE COURT: Or depositions.

15 MS. ANDERSEN: Or depositions. Right. But I  
16 have had almost -- I don't think I've had a single case  
17 proceed to trial where outside counsel did not have access  
18 to confidential information of all the parties.

19 THE COURT: Mr. Deming raised an issue about  
20 experts. I mean, he acknowledged that he wasn't a  
21 competitive decision-maker, and I think he has acknowledges  
22 that you are not.

23 MS. ANDERSEN: I am not, Your Honor.

24 THE COURT: He doesn't know your experts. And  
25 presumably, if you pick an expert that's a competitive

1 decision-maker, he's going to knock on the Court's door and  
2 ask that you not be able to go forward, I would think. Do  
3 you agree?

4 MS. ANDERSEN: That's correct, and that's  
5 provided for in the protective order.

6 THE COURT: Now, what about the problem of or  
7 the potential for defendants to have a competitive  
8 decision-maker expert or an expert who is a competitive  
9 decision-maker relative to a co-defendant? How do we  
10 address that?

11 MS. ANDERSEN: Understood, Your Honor. So the  
12 provision in the protective order right now says that the  
13 expert disclosure will be served on all parties, so that's  
14 all defendants. So if there's an objection by one of the  
15 defendants, that will be taken in accordance with the  
16 objection procedure that the parties have already agreed to  
17 in the protective order.

18 THE COURT: And that would have to predate the  
19 disclosure of information to an expert. Correct?

20 MS. ANDERSEN: Yes Your Honor.

21 THE COURT: Is it built in that there's a  
22 certain period of time by which an objection can be lodged  
23 before any disclosures can be made?

24 MS. ANDERSEN: Yes, Your Honor.

25 THE COURT: Thank you. Go ahead.

1 disclosure, especially since we're in the exact same boat as  
2 plaintiffs' counsel.

3 THE COURT: All right. Has subsequent  
4 prosecution bar been discussed?

5 MS. ANDERSEN: Yes, Your Honor, and agreed to.  
6 I should say for clarification, Exhibit A to our letter is  
7 our proposed protective order.

8 Everything --

9 THE COURT: I was going to tell you, basically,  
10 because of what I had talked about at the very beginning, I  
11 didn't really look at your protective order because I did  
12 not think it was appropriate. Well, I wasn't going to  
13 spend -- I've got too many things to do. I wasn't going to  
14 try to figure out if they're the exact same orders. I read  
15 the two paragraphs that are recited explicitly in  
16 defendants' letter and that's what I looked at.

17 MS. ANDERSEN: Understood, Your Honor. We  
18 apologize.

19 THE COURT: No. I just want to tell you why I  
20 don't know about it.

21 MS. ANDERSEN: Of course. But the prosecution  
22 bar and the -- we have an FDA bar as well. That has already  
23 been negotiated and already been agreed to.

24 THE COURT: Okay. Mr. Deming, you have  
25 30 seconds to a minute if you have any rebuttal. Thank you,

1 MS. ANDERSEN: You know, I don't want to belabor  
2 the point.

3 THE COURT: On that point, I don't think you do  
4 need to belabor it. You can move on.

5 MS. ANDERSEN: All right. We think really what  
6 this is about, we talked a lot about the use of information,  
7 which I think more favorably is an evidentiary question.

8 This is really about the risk, the risk to  
9 defendants here, and we just don't think the defendants have  
10 carried their burden on that. I think, as Your Honor  
11 rightfully noted, we're talking about outside counsel, the  
12 outside counsel sitting in this room. I know that we take  
13 our confidentiality obligations very seriously. We know  
14 that defendants' outside counsel does as well.

15 And we understand that generics at some point  
16 may be direct competitors to each other in this marketplace,  
17 but this entire litigation is about whether defendants are  
18 able to compete with plaintiffs in the market for Imbruvica,  
19 and despite that, we have to disclose very sensitive  
20 research and development. I mean, hundreds of thousands of  
21 pages of R&D, business, financial records not only to  
22 defendants' outside counsel, but to defendants' in-house  
23 counsel as well.

24 So we just don't see how there is some  
25 substantial risk here for, you know, even for inadvertent

1 Ms. Anderson.

2 MS. ANDERSEN: Thank you.

3 MR. DEMING: Thank you, Your Honor. Now I will  
4 focus on the most important points, Your Honor.

5 Plaintiffs' counsel mentioned proceeding to  
6 trial, and, again, as I mentioned, the expectation is  
7 counsel is going to, we're going to work this out where  
8 we're going to be able to have a common trial and it's going  
9 to be to work smoothly.

10 I did want to bring to Your Honor's attention  
11 the September 2018, you mentioned earlier, Judge Stark. As  
12 I noted, he left the door open for defendants' proposed new  
13 language, and it's my understanding that they did, in fact,  
14 propose narrower language, and that issue is back before him  
15 pending right now.

16 And so, you know, I think, Your Honor, that we  
17 may see an order. If the order from yesterday is any  
18 indication, we may see a follow-up order on that September  
19 order granting the relief that the defendants are seeking  
20 here, and I think that would be consistent with entering  
21 an order along the lines that we're asking for in this  
22 case.

23 Unless Your Honor has any other questions, I  
24 will --

25 THE COURT: Last question I have for you. Your



1 letter didn't mention it, but the burden is on you to show  
2 good cause. Correct?  
3 MR. DEMING: I believe that's right, Your Honor.  
4 We're seeking a protective order. And I think on that note,  
5 Your Honor, I disagree with plaintiffs that there's no risk  
6 here. It sounded like until that last part, everyone has  
7 acknowledged --

8 THE COURT: I didn't understand her point to be  
9 that. I think the point is kind of the risk of inadvertent  
10 disclosure exists with you and all the other counsel sitting  
11 at the table and it exists with plaintiffs' counsel. But  
12 that's a risk that, as I understand the point, it's in all  
13 litigation.

14 MR. DEMING: Well, I think the relationship is a  
15 little bit different because the defendants are all  
16 competing to get on the market. We're not there yet. And I  
17 mean, there's eight of us, and so whoever is first could  
18 have a real significant advantage over whoever is eighth.  
19 And so that's why there's a real competitive risk.

20 THE COURT: Even your thing, they could put it  
21 in a court filing. At the end of the day, something like  
22 that could go in a court filing. So even you have to  
23 acknowledge, I mean, there are limitations on what you are  
24 going to do there and there are provisions in the current  
25 protective order to address that risk. Is that correct?

1 is a direct competitor to your client. Right?  
2 MR. DEMING: We could evaluate it that much.  
3 What I'm saying, that objection period could run and then we  
4 could find out later that when another defendant's  
5 information is revealed to us for the first time, now we  
6 determine there's a conflict. If the period had ran  
7 already, we have no way of knowing that information is  
8 out there. That could be a sleeping issue that could  
9 arise.

10 THE COURT: All right.

11 MR. DEMING: Thank you, Your Honor.

12 THE COURT: All right. Let's move to Cipla.  
13 We're going to have much less time for this argument.

14 MR. BERNSTEIN: Okay.

15 THE COURT: I think it's pretty straightforward.  
16 If you could just identify yourself.

17 MR. BERNSTEIN: Steve Bernstein. Thank you,  
18 Your Honor.

19 So the issue that I'm here to raise with you  
20 today is that Cipla would like to have one of the people  
21 under the protective order who can receive plaintiffs'  
22 confidential information to be a non-attorney, and under the  
23 protective order, infringement has not been agreed upon  
24 between the parties.

25 Each party designate three in-house counsel to

1 MR. DEMING: Your Honor, there's always risk.  
2 We're just trying to do what we can to minimize it.

3 THE COURT: All right.

4 MR. DEMING: And the relationship with  
5 plaintiffs, they are on the market already. Their product  
6 is finished, it's final, and while they may be disclosing  
7 some of the similar types of information, it's really not  
8 apples to apples.

9 THE COURT: All right. The last thing I just  
10 want to make sure. Do you agree that if one of your  
11 co-defendants were to identify an expert who is a  
12 competitive decision-maker to your client, you would have  
13 enough, you could come to court right away and prevent the  
14 plaintiffs from disclosing information to that expert? Is  
15 that correct?

16 MR. DEMING: Your Honor, I don't know if we  
17 would have all the information necessary to make that  
18 evaluation because we don't know what information the other  
19 defendants have. And so, and that's where we're at this --  
20 you know, that information.

21 If Sandoz --

22 THE COURT: I'm never going to get over that. I  
23 thought you were going to agree with me on this. I mean, if  
24 a co-defendant identifies Joe Smith as an expert, you can do  
25 some quick background check and determine whether Joe Smith

1 receive --

2 THE COURT: Up to three.

3 MR. BERNSTEIN: Up to three in-house counsel to  
4 receive confidential information. Cipla would like to  
5 designate two attorneys to receive confidential information,  
6 and those are, and this is a clarification I think we might  
7 have had an understanding with plaintiffs during our  
8 meet-and-confer process, but those attorneys are non-U.S.  
9 attorneys. Those are attorneys in India. And they would --  
10 someone would like to designate the third person to be a  
11 non-U.S. attorney -- a non-U.S. non-attorney, and that  
12 person that would actually report to the two other people,  
13 the two other non-U.S. attorneys who are in a supervisory  
14 role. Cipla can handle multiple litigations in that  
15 supervisory role.

16 THE COURT: Okay. Is this person a competitive  
17 decision-maker?

18 MR. BERNSTEIN: This person is not a competitive  
19 decision-maker. This person is not involved in patent  
20 prosecution. This patent is not involved in marketing.  
21 This person is not involved in research and development.  
22 So, no, we don't believe that this person is a competitive  
23 decision-maker.

24 THE COURT: All right.

25 MR. BERNSTEIN: We also think that it's

1 certainly aspects, many aspects of the case she'll be able  
2 to participate in. Cipla's confidential information will be  
3 used for infringement. She'll have access to that.  
4 Validity in part is going to rely on public documents like  
5 articles, references. She'll have access to that. And then  
6 there's an in-house attorney.

7 Thank you, Your Honor.

8 THE COURT: Thank you very much.

9 All right. So I'm going to deny the defendants'  
10 applications starting with the second issue for Cipla.

11 I do think it's important that the person be an  
12 attorney because that person, as I think the case law is  
13 clear, is subject to ethical and professional obligations  
14 and sanctions that a non-attorney is not, and the burden  
15 rests on Cipla, and they have not -- Cipla, rather, has not  
16 persuaded me that good cause here exists to add this person,  
17 or make this person of attorney status even though the  
18 person is not attorney status, and I don't believe that  
19 Cipla's staffing preferences here outweigh the competing  
20 confidentiality concerns that the plaintiff I think  
21 understandably has.

22 As far as the protective order issue, again, the  
23 burden rests with the defendant to show that good cause  
24 exists for these high end confidentially or nondisclosure  
25 provisions they've proposed. Given that plaintiffs are

1 expert restriction should be adopted in whatever ultimate  
2 protective order is presented to me, and that the  
3 defendants' proposed provisions for the protective order  
4 should not be included in the ultimate protective order.  
5 And then, similarly, that the non-attorney person from Cipla  
6 should not be allowed the same access to the outside  
7 attorneys and expert.

8 Does that resolve all the disputes before me  
9 currently?

10 MR. DEMING: I believe so, Your Honor.

11 MS. ANDERSEN: I believe so as well, Your Honor.

12 THE COURT: Okay. Thank you very much. Are  
13 there any other issues?

14 MS. ANDERSEN: Your Honor, just one brief issue.  
15 We understand that you have a form scheduling order. There  
16 are some departures, for example, the Markman proceeding  
17 from what we had entered into with Judge Sleet, and  
18 plaintiffs were wondering how you would like to handle that,  
19 if you wanted us to work with defendants to submit a new  
20 scheduling order, or how that is best to be handled.

21 THE COURT: Yes. I glad you raised it. I  
22 forgot.

23 So I do need you all to submit a revised  
24 scheduling order. It should reflect the current discovery  
25 limitations and dates that are in effect. However, there's

1 limiting disclosures to outside counsel and experts, I have  
2 not been persuaded that the risk of inadvertent disclosure  
3 here increases sufficiently to warrant the relief that the  
4 defendants are seeking. I think it is unfair well to the  
5 plaintiffs.

6 The plaintiff is, of course, a competitor of the  
7 defendants' and yet we're allowing or requiring disclosures  
8 to be made between plaintiff and the defendant subject to  
9 the limitations on outside attorneys and experts, and I  
10 think to impose this ban on cross disclosures would require  
11 revelation of the attorney's work product that the  
12 plaintiffs have. I think it would create administrative  
13 burdens on the Court because I think the issues, if the  
14 defendants' protective order were to be adopted, these  
15 issues, disputes that would follow would create not only  
16 unfair burdens and impositions on the plaintiffs, but they  
17 would eventually come to the Court's attention.

18 I hear and appreciate Ms. Clayton's argument  
19 that there could be disputes down the road, but my sense is  
20 that those disputes would be fewer and could be more easily  
21 resolved by the Court, but that I do appreciate that  
22 argument.

23 Therefore, I don't have a form order in front of  
24 me, so what I will do is just allow the transcript to  
25 reflect the order of the Court that the plaintiffs' attorney

1 probably simultaneous Markman briefing in the current order.  
2 Is that right?

3 MS. ANDERSEN: I think that's right, Your Honor,  
4 yes.

5 THE COURT: Okay.

6 MS. ANDERSEN: I think it's two rounds of  
7 simultaneous briefing.

8 THE COURT: So that you are going to have to  
9 back up. You are going to have to provide -- and I'm not a  
10 hundred percent sure I can keep the Markman. I'm not a  
11 hundred percent sure I can keep the dates, but if you want  
12 the dates as they currently exist for the Markman, you have  
13 to back up and have the single brief submitted no less than  
14 30 days before the scheduled Markman hearing.

15 MS. ANDERSEN: Understood, Your Honor.

16 THE COURT: Okay. I also just made a revision  
17 this morning to the procedures tab on my web page. I would  
18 like two courtesy copies of letters. Some people are only,  
19 I think this is the case, I only got one. I'm not faulting  
20 anybody because I said briefs and maybe you understood these  
21 not to be briefs. Just going forward, it really helps if I  
22 can have two courtesy copies. It makes it easier in  
23 chambers.

24 MS. ANDERSEN: Understood, Your Honor.

25 I think one other small ministerial thing. All

# EXHIBIT F

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

AMGEN INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 16-853 (GMS)
	)	CONSOLIDATED
AUROBINDO PHARMA LTD., et al.,	)	
	)	
Defendants.	)	

**STIPULATED PROTECTIVE ORDER**

WHEREAS discovery in the above-captioned related proceedings (the “Actions”) may involve the disclosure of certain documents, things, and information in the possession, custody or control of Amgen, Inc. (“Amgen” or “Plaintiff”), or Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc.; Micro Labs Ltd. and Micro Labs USA Inc.; Watson Laboratories, Inc. and Actavis Pharma, Inc.; Cipla USA, Inc. and Cipla Limited; Strides Pharma Global PTE Ltd. and Strides Pharma, Inc.; Sun Pharma Global FZE, Sun Pharmaceutical Industries, Inc., and Sun Pharmaceutical Industries, Ltd.; Ajanta Pharma Ltd. and Ajanta Pharma USA Inc.; Dr. Reddy’s Laboratories, Inc. and Dr. Reddy’s Laboratories, Ltd.; Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC; Apotex Corp. and Apotex Inc.; Breckenridge Pharmaceutical, Inc.; Hetero USA Inc., Hetero Labs Ltd. and Hetero Labs Ltd. Unit V; Mylan Pharmaceuticals Inc. and Mylan Inc.; Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. (collectively, “Defendants”) or other persons that constitute or contain sensitive proprietary information, such as trade secrets or other confidential research, development, or commercial information, within the meaning of Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure;

WHEREAS such trade secret, confidential, or proprietary information must be protected in order to preserve the legitimate business interests of the parties or other persons;

9. Nothing in this Protective Order shall bar or otherwise restrict counsel from rendering advice to his or her client with respect to these Actions and, in the course thereof, relying in a general way upon his or her examination of Designated Information produced or exchanged in these Actions; provided, however, that in rendering such advice and in otherwise communicating with a person not entitled to access Designated Information, the attorney shall not disclose the contents of Designated Information produced by any other party or non-party to anyone not authorized under this Protective Order to receive the Designated Information.

10. Non-parties may designate as CONFIDENTIAL or HIGHLY CONFIDENTIAL deposition transcripts of their witnesses and any documents or information they produce, whether voluntarily or by subpoena, to the same extent and in the same manner as parties to these Actions and any such Designated Information shall be treated by the parties to these Actions in the same manner as Designated Information so designated by a party. Non-parties shall have the same rights and obligations under this Protective Order as parties and may move the Court to enforce the provisions of this Protective Order.

11. Nothing in this Protective Order precludes a Producing Party from using or disseminating its own Designated Information.

### **DISCLOSURE**

12. The term “Qualified Person” means:

- a. Outside counsel of record who have made an appearance in this Action, and employees at their firms;
- b. No more than three specifically-designated “In-House Counsel” (of the Receiving Party) per Party, where “In-House Counsel” is defined as U.S. attorneys admitted to practice in the U.S. Such In-House Counsel shall have a need to know the Designated Information to fulfill his or her duties and responsibilities in connection with this litigation, and

meet the requirements of Paragraph 15, as well as paralegals, assistants, in-house information technology providers, and clerical employees who support such in-house personnel. For each respective Party, the specifically identified In-House Counsel and their titles are set forth as follows (if not listed below, names and titles will be provided at least ten (10) business days prior to any such In-House Counsel being provided access to CONFIDENTIAL or HIGHLY CONFIDENTIAL INFORMATION):

- i. For Amgen Inc.:
  1. Wendy A. Whiteford (Vice President, Law)
  2. Lois M. Kwasigroch (Senior Counsel)
- ii. For Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC:
  1. Ken Zeidner (Senior Patent Counsel/Senior Director – Global Intellectual Property)
  2. Lars Taavola (Senior Director/Senior Patent Counsel – Global Intellectual Property)
  3. Bryan Sommese (Director, Global Intellectual Property)
- iii. For Apotex Corp. and Apotex Inc.:
  1. Omar Jabri (Senior Patent Attorney, Global Intellectual Property)
- iv. For Breckenridge Pharmaceutical, Inc.:
  1. Bruce DeRenzi (Director – Litigation Counsel)
  2. Robert Vroom (Litigation Counsel)
- v. Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd.
  1. Andrew J. Allen (Director, Legal Counsel – Intellectual Property)

2. Anjum Swaroop (Vice President, Intellectual Property)
- vi. For Mylan Pharmaceuticals Inc. and Mylan Inc.:
  1. Preston Imperator (Litigation Counsel)
  2. Tom Jenkins (Assistant General Counsel)
- vii. For Sun Pharma Global FZE, Sun Pharmaceutical Industries, Inc., and Sun Pharmaceutical Industries, Ltd.:
  1. Craig Kuchii (Senior Director, Intellectual Property)
- viii. For Watson Laboratories, Inc. and Actavis Pharma, Inc.:
  1. Lauren Rabinovic (Vice President and General Counsel, North American Generic IP)
  2. Jonathan R. Wise (Associate General Counsel, U.S. IP Litigation)

The Parties may, as necessary, substitute on a one-for-one basis other In-House Counsel meeting the above criteria for the above-listed individuals, provided that the substituting Party gives the other Parties ten (10) business days' notice prior to said substitution.

c. Current or former employees of any Party who are authors, addressees, or recipients of the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION;

d. Outside independent experts and consultants of the Receiving Party who are assisting outside counsel of record for the Receiving Party in this action and any necessary assistants and stenographic and clerical employees under their direct supervision and employed by them or their employer or organization, provided that the requirements of Paragraphs 16-17 are satisfied; and

e. The Court and Court personnel, including stenographic reporters

f. Professional vendors who are assisting outside counsel of record for the Receiving Party in this action; and

g. Others as to whom the Producing Party has given written consent, subject to the requirements and procedures of Paragraphs 13 through 17.

13. Discovery Material designated as CONFIDENTIAL may be disclosed by the Receiving Party only to Qualified Persons as set forth in Paragraph 12 above, as well as the officers, directors, and employees of the Receiving Party to whom disclosure is reasonably necessary for this litigation provided that at least ten (10) business days prior to the Receiving Party giving, showing, disclosing, making available or communicating CONFIDENTIAL INFORMATION, the individual to whom the CONFIDENTIAL INFORMATION is to be provided shall be identified to the Producing Party by both name and title. Prior to any such disclosure of CONFIDENTIAL INFORMATION to Qualified Person under Paragraph 12, as well as the officers, directors, and employees of the Receiving Party to whom disclosure is reasonably necessary for this litigation, the requirements of Paragraphs 16-17 shall be satisfied. Designated Information of one Defendant may not be disclosed to another Defendant's In-House Counsel, unless otherwise agreed.

14. Discovery Material designated as HIGHLY CONFIDENTIAL INFORMATION may be disclosed only to Qualified Persons. Designated Information of one Defendant may not be disclosed to another Defendant's In-House Counsel, unless otherwise agreed.

15. Any individual who receives Discovery Material designated CONFIDENTIAL or HIGHLY CONFIDENTIAL shall not, while these Actions are pending and for a period of 18 months after their conclusion including all appeals, on behalf of any party other than the Producing Party (a) draft or prosecute, or provide counseling regarding the drafting or prosecution of, any patent application anywhere in the world relating to cinacalcet



# EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

T-JAT SYSTEMS 2006 LTD.,

Plaintiff,

v.

EXPEDIA, INC. (DE) and ORBITZ  
WORLDWIDE, INC.,

Defendants.

C.A. No. 16-cv-581-RGA

ORDER

Presently before the Court is the issue of whether two of T-Jat's employees, Dr. Golobrodsky and Mr. Vershavsky, may access documents designated Attorney's Eyes Only (AEO). I have considered the parties' papers. (D.I. 76, 77, 82, 84). I held a discovery conference on October 15, 2018.

Inherent in a court's power under Federal Rule of Civil Procedure 26 is the ability to restrict an individual's access to confidential information when there is "an unacceptable opportunity for inadvertent disclosure." *See U.S. Steel Corp. v. United States*, 730 F.2d 1465, 1468 (Fed. Cir. 1984). The Federal Circuit has made clear that limits to attorney access should be judged on "a counsel-by-counsel basis, and cannot be determined solely by giving controlling weight to the classification of counsel as in-house rather than retained." *Id.* "[T]he counsel-by-counsel determination should turn on the extent to which counsel is involved in 'competitive decisionmaking' with its client." *In re Deutsche Bank Trust Co. Ams.*, 605 F.3d 1373, 1378 (Fed. Cir. 2010). Competitive decisionmaking is "shorthand for a counsel's activities,

association, and relationship with a client that are such as to involve counsel's advice and participation in any or all of the client's decisions (pricing, product design, etc.) made in light of similar or corresponding information about a competitor." *Id.* (quoting *U.S. Steel*, 730 F.2d at 1468 n.3). Even if a court is satisfied that a risk of inadvertent disclosure or misuse exists, the court "must balance this risk against the potential harm to the opposing party" in deciding the scope of the protective order. *Id.* at 1380.

Although T-Jat does not have in-house counsel and is requesting access for non-attorney employees, I believe the principles set out in *U.S. Steel* still apply. *See, e.g., McAirloads, Inc. v. Kimberly-Clark Corp.*, 299 F.R.D. 498, 500–01 (W.D. Va. 2014). Whether "an unacceptable opportunity for inadvertent disclosure" exists depends on the extent to which Dr. Golobrodsky and Mr. Vershavsky are involved in competitive decisionmaking at T-Jat. This risk of inadvertent disclosure should then be balanced against the potential harm to T-Jat if Dr. Golobrodsky and Mr. Vershavsky cannot access the AEO materials.

T-Jat suggests a different framework altogether. T-Jat cites to three cases, all by the same judge, that say essentially the same thing. That is, it was the practice of the judge to give at least one person "from the company" access to all the documents. (D.I. 77 at 3). It may be that all three cases reached the right result, but I think T-Jat attempts to make the judge's practice into a legal rule. I do not think the case law supports such a finding. For example, in *Safe Flight Instrument Corp. v. Sundstrand Data Control Inc.*, 682 F. Supp. 20 (D. Del. 1988), the court cites numerous cases for the proposition that a party's "technical information" would only be disclosed to opposing "trial counsel" and "independent experts" despite the opposing party's request that it be submitted to at least one employee of the opposing party. *Id.* at 22. Likewise, other courts in more recent cases have declined to allow client employees access to confidential

information when those employees are competitive decisionmakers. *See McAirlaids*, 299 F.R.D. at 501; *3M Co. v. ACS Indus., Inc.*, 2015 WL 13484695, at \*2–3 (D. Minn. Dec. 2, 2015); *Wanke Cascade Distrib. Ltd. v. Forbo Flooring, Inc.*, 2014 WL 12648465, at \*2–3 (D. Or. Apr. 11, 2014).

Here, unlike in much of the case law, the parties are not direct competitors. *See, e.g., Safe Flight*, 682 F. Supp. at 21. Therefore, additional analysis is required to determine what harm to Defendants, if any, might result from inadvertent disclosure.<sup>1</sup> T-Jat argues that neither Dr. Golobrodsky nor Mr. Vershavsky are competitive decisionmakers “in the sense of any competition with Expedia.” (D.I. 77 at 2). I disagree. The parties’ market relationship, though relevant, is not dispositive of whether T-Jat’s employees are competitive decisionmakers. *See Blackbird Tech LLC v. Serv. Lighting & Elec. Supplies, Inc.*, 2016 WL 2904592, at \*4 (D. Del. May 18, 2016). I think the key question is whether “Defendants’ trade secrets and other sensitive information could potentially be of value to [T-Jat].” *R.R. Donnelley & Sons Co. v. Quark, Inc.*, 2007 WL 61885, at \*2 n.2 (D. Del. Jan. 4, 2007).

Defendants’ “core technical documents,” produced as an example of materials that Defendants would designate as AEO, show a detailed presentation on Expedia’s backend systems. (D.I. 82 at 1, Exs. 7–10). Defendants assert, “[I]t will be challenging for T-Jat not to use that information in connection with its own business.”<sup>2</sup> (*Id.* at 1). On the other hand, T-Jat

---

<sup>1</sup> I believe this is a preliminary issue. If inadvertent disclosure by T-Jat’s employees poses no risk of harm to Defendants, Defendants will fail to show good cause for the proposed protective order irrespective of the employees’ decisionmaking power. This is consistent with the Federal Circuit’s definition for competitive decisionmaker, which asks to what extent one influences the client’s decisions in light of “information about a *competitor*.” *U.S. Steel*, 730 F.2d at 1468 n.3 (emphasis added).

<sup>2</sup> In an earlier letter Defendants also argued that “the technology Expedia will disclose is the focus of at least one of the products T-Jat markets,” and “T-Jat has long been involved in litigation and licensing involving the asserted patents and has said that it intends to bring additional lawsuits.” (D.I. 76 at 1–2). During the discovery conference, however, T-Jat denied both allegations and Defendants indicated that

argues that there is no risk of competition, because it “markets a platform to enable simultaneous web access from multiple devices and communication channels” while Expedia provides “travel-related services and software.” (D.I. 77 at 1).

Based on the present record, it is not clear exactly what value T-Jat may derive from Defendants’ confidential information. But, it appears that both T-Jat and Expedia provide technology-based products/services. Given the fact that this is a patent infringement action, it seems likely that, even if T-Jat and Expedia do not have competing products/services, they employ overlapping technology in those products/services. Therefore, the parties share an interest in the same technological field. T-Jat would gain a competitive advantage if it inadvertently used knowledge from Defendants’ AEO materials in its own research and development.<sup>3</sup> Therefore, I think Defendants have shown a sufficient likelihood of harm from inadvertent disclosure to require further analysis of whether Dr. Golobrodsky and Mr. Vershavsky are competitive decisionmakers.

I believe Dr. Golobrodsky is a competitive decisionmaker. Dr. Golobrodsky is T-Jat’s Chief Science Officer and oversees “technical operations.” In addition, he is a founder, shareholder, and listed inventor on both asserted patents. T-Jat represented during the discovery conference that it has about ten employees in total, including employees at related companies. It seems probable that Dr. Golobrodsky plays a large role in most, if not all, of T-Jat’s technical decisions. Therefore, I find it likely that Dr. Golobrodsky has both the expertise and

---

they know very little about T-Jat’s business. I do not think T-Jat gave a clear explanation of its business in the papers or during the discovery conference.

<sup>3</sup> T-Jat represented at the discovery conference that its patent portfolio with the asserted patents is “mature,” and that the only patent it is currently prosecuting covers an unrelated technology. Therefore, any risk of competitive advantage will likely relate to T-Jat’s use, rather than patenting, of Defendants’ technology.

management control to inadvertently use the information from Defendant's AEO materials to T-Jat's competitive advantage.

Mr. Vershavsky does not appear to be a competitive decisionmaker, at least to the same extent as Dr. Golobrodsky. Mr. Vershavsky is a shareholder in a related company and a "qualified technician." (D.I. 77 at 2). He works at T-Jat "in the capacity of operations, high level quality assurances, and overall logistical support," and "is not involved in any management capacity." (*Id.*). Unlike Dr. Golobrodsky, Mr. Vershavsky seems to have limited control over which technologies T-Jat pursues and how that technology is monetized.

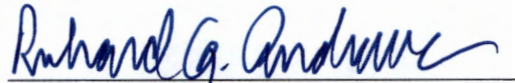
T-Jat argues that Dr. Golobrodsky and Mr. Vershavsky need to have access to the AEO materials to effectively decide "case strategy" and "assist in the technical aspects of the case." (D.I. 77 at 2). "The risk of inadvertent disclosure cannot be overcome by the mere contention that access to confidential information is necessary for case management." *R.R. Donnelley*, 2007 WL 61885, at \*1. Further, I doubt that either Dr. Golobrodsky or Mr. Vershavsky are uniquely qualified to "assist in the technical aspects of the case"—the same role could be played by a third-party expert. Although Mr. Vershavsky does not appear to have the same decisionmaking power as Dr. Golobrodsky, I believe, given his technical expertise and T-Jat's small size, there is still a risk that he will inadvertently apply the technical knowledge acquired from Defendants' AEO materials to T-Jat's advantage. "It is very difficult for the human mind to compartmentalize and selectively suppress information once learned, no matter how well-intentioned the effort may be to do so." *In re Deutsche Bank*, 605 F.3d at 1378 (citation and brackets omitted). Therefore, on balance, I think the risk of harm to Defendants from inadvertent disclosure outweighs any harm to T-Jat from not having Dr. Golobrodsky and Mr. Vershavsky access the confidential information. It should not be an unacceptable hardship for T-Jat to rely



on litigation counsel and outside experts to review the AEO materials. “This is a necessary consequence of achieving a balance between full disclosure in discovery and protection against economic injury.” *McAirlaids*, 299 F.R.D. at 501–02.

The parties should resubmit the proposed protective order in conformity with this Order.

IT IS SO ORDERED this 19 day of October 2018.

  
United States District Judge

# EXHIBIT 2



**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

ASTRAZENECA LP, ASTRAZENECA AB,  
ASTRAZENECA UK LIMITED, and  
ASTRAZENECA PHARMACEUTICALS LP,

Plaintiffs,

v.

SIGMAPHARM LABORATORIES, LLC,

Defendant.

Civil Action No.: 15-1000-RGA  
(CONSOLIDATED)

**STIPULATED PROTECTIVE ORDER**  
**PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 26(c)**

WHEREAS, Mylan Pharmaceuticals Inc. (“Mylan”) is named Defendant in Civil Action Nos. 15-0999-RGA and 15-1000-RGA.

WHEREAS, Sigmapharm Laboratories, LLC (“Sigmapharm”) is named Defendant in Civil Action No. 15-1000-RGA.

WHEREAS, InvaGen Pharmaceuticals, Inc. (“InvaGen”) is named Defendant in Civil Action Nos. 15-1000-RGA and 15-1001-RGA.

WHEREAS, Watson Laboratories, Inc. (“Watson”) is named Defendant in Civil Action Nos. 15-1000-RGA and 15-1002-RGA.

WHEREAS, HEC Pharm Co., Ltd., HEC Pharm Group, and HEC Pharm USA, Inc. (collectively, “HEC”) are named Defendants in Civil Action Nos. 15-1000-RGA and 15-1041-RGA.

WHEREAS, Amneal Pharmaceuticals LLC, and Amneal Pharmaceuticals of New York, LLC (collectively, “Amneal”) are named Defendants in Civil Action Nos. 15-1000-RGA and 15-1056-RGA.

WHEREAS, Princeton Pharmaceutical Inc. (“Princeton”) is named Defendant in Civil Action Nos. 15-1000-RGA and 15-1057-RGA.

WHEREAS, Apotex Inc. and Apotex Corp. (collectively “Apotex”) are named Defendants in Civil Action Nos. 15-1000-RGA and 15-1058-RGA.

WHEREAS, AstraZeneca LP, AstraZeneca AB, AstraZeneca UK Limited, and AstraZeneca Pharmaceuticals LP (collectively, “AstraZeneca” or Plaintiffs) are named plaintiffs in the actions mentioned above (“the Actions”);

WHEREAS, in the course of this Action, one or more of the AstraZeneca Plaintiffs may seek disclosure of information that Mylan, Sigmapharm, InvaGen, Watson, HEC, Amneal, Princeton, and/or Apotex (collectively “Defendants”) regard as proprietary or confidential trade secret, technical, business, financial, or personnel information;

WHEREAS, in the course of this Action, any of Defendants may seek disclosure of information that one or more of the AstraZeneca Plaintiffs regards as proprietary or confidential trade secret, technical business, financial, or personnel information;

WHEREAS, in the course of this Action, any of Defendants, and/or Plaintiffs may seek disclosure of third-party information to any one of them which the third party regards as proprietary or confidential trade secret, technical, business, financial, or personnel information; and

WHEREAS, the parties to the Actions desire to establish a mechanism to protect and govern the use of any disclosure of such proprietary or confidential trade secret, technical, business, financial, or personnel information;

IT IS HEREBY STIPULATED by and among the parties hereto, by their respective undersigned counsel of record, that this Stipulated Protective Order shall govern the disclosure of

proprietary or confidential trade secret, technical, business, financial, or personnel information in this Action.

### **DEFINITIONS**

1. “Order” and “Protective Order” mean this Stipulated Protective Order.
2. “Party” means any named party to this Action and any entities that have agreed to be bound by discovery; where more than one related entities are a defendant or plaintiff, those related entities shall be considered a singular Party.
3. “Third Party” means a person or entity who is not a party to this Action and who is requested to provide information or testify in connection with this Action or whose information is disclosed in this Action.
4. The “Action” means Civil Actions that have been consolidated for pre-trial and validity purposes into Civil Action No. 15-1000-RGA. “Related infringement actions” include Civil Action No. 15-0999-RGA; Civil Action No. 15-1000-RGA; Civil Action No. 15-1001-RGA; Civil Action No. 15-1002-RGA; Civil Action No. 15-1041-RGA; Civil Action No. 15-1056-RGA; Civil Action No. 15-1057-RGA; and Civil Action No. 15-1058-RGA.
5. “CONFIDENTIAL INFORMATION” means any information, document, or thing, or portion of any document or thing: (a) that contains private or confidential personal information, (b) that contains information received in confidence from third parties, or (c) which the producing party otherwise believes in good faith to be entitled to protection under Rule

26(c)(1)(G) of the Federal Rules of Civil Procedure. Any Party to this litigation or any Third Party covered by this Order who produces or discloses any CONFIDENTIAL INFORMATION, including without limitation any information, document, thing, interrogatory answer, admission, pleading, or testimony, shall mark the same with the foregoing or similar legend: “CONFIDENTIAL”.

6. “HIGHLY CONFIDENTIAL INFORMATION” means any information, document, or thing, or portion of any document or thing that contains highly sensitive business or personal information, the disclosure of which is highly likely to cause significant harm to an individual or to the business or competitive position of the designating party, and shall include, without limitation, highly sensitive or highly proprietary technical or business information including information concerning (a) research and development, formulation, patent applications, strategic plans, financial, manufacturing, and marketing plans; (b) a party’s or third-party’s ownership, organization, management, financial planning and financial performance; (c) a Party’s or Third Party’s current products, processes, business plans, competitive strategies, or business relationships (including past information indicative of current practices); (d) a Party’s or Third Party’s potential future products, processes, business plans, competitive strategies, or business relationships; (e) new drug applications or abbreviated new drug applications; (f) personal information, patient information or personal health information including information protected under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”); (g) physical samples provided through discovery; (h) data, reports, notes, or other documentation generated in the testing or analysis of the physical samples provided through discovery (“Derivative Testing Information”); (i) any part of a Drug Master File, Chemistry

Manufacturing and Controls, and any formulation descriptions (e.g., the identity and proportions of inactive ingredients) in an Abbreviated New Drug Application (“ANDA”), an Investigational New Drug, and/or a New Drug Application of a party; and (j) parties’ launch plans. Other confidential trade secrets or business information not falling into one of these enumerated categories may be designated as “Confidential Information” or “Highly Confidential Information” as appropriate. Any party to this litigation or any third party who is covered by this Order, who produces or discloses any Highly Confidential material, including without limitation any information, document, thing, interrogatory answer, admission, pleading, or testimony, shall mark the same with the foregoing or similar legend: “HIGHLY CONFIDENTIAL”.

7. CONFIDENTIAL INFORMATION and HIGHLY CONFIDENTIAL INFORMATION shall not include:

- a. information that is in the public domain at the time of disclosure;
- b. information that after disclosure is published or becomes part of the public domain through no fault of a person receiving information under this Order, but only after it is published or comes into the public domain;
- c. information that is already in the possession of a Party receiving such information without any confidentiality obligations at the time of disclosure;
- d. information disclosed by a Third Party that is not subject to any confidentiality obligations at the time of the disclosure; or
- e. information that was, is, or becomes expressly released from being designated CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION, by the Producing Party or by order of the Court.



8. "PROTECTED INFORMATION" means "CONFIDENTIAL INFORMATION" and/or "HIGHLY CONFIDENTIAL INFORMATION."

9. "Outside Counsel" means outside attorneys of record and attorneys serving under their direct supervision, including but not limited to outside attorneys admitted *pro hac vice* in this Action and their respective stenographic, clerical, and legal assistant employees.

10.

~~[Plaintiffs' proposal: "Designated In-House Representative" means an attorney in the legal or patent department of a Party with litigation oversight responsibilities. The number of individuals specified as "Designated In-House Representative" shall be limited to a maximum of two in-house attorneys for each Party. Any such in-house representatives will execute an undertaking as set forth in Exhibit A acknowledging the terms of this Order and agreeing to be bound by it.]~~

RGA

~~[Defendants' proposal: "Designated In-House Representative" means an attorney in the legal or patent department of a Party with litigation oversight responsibilities or, in the case of a Defendant that lacks in-house attorneys in its legal or patent department, a non-attorney employed by that Defendant with litigation oversight responsibilities. The number of individuals specified as "Designated In-House Representative" shall be limited to a maximum of two in-house attorneys/non-attorneys for each Party. Any such in-house representatives will execute an undertaking as set forth in Exhibit A acknowledging the terms of this Order and agreeing to be bound by it.]~~

7

**TERMS OF THE ORDER**

**11. *Use of PROTECTED INFORMATION***

Except by consent of the producing Party or order of this Court and subject to the provisions of Paragraphs 16 and 26 hereof, a Party or person bound by this Order shall not (1) use any PROTECTED INFORMATION received pursuant to this Order for any purpose other than this Action, including without limitation any other litigation, research, development, manufacture, submissions to the U.S., European or any other Pharmacopoeia, marketing purpose, regulatory purpose, patent prosecution or acquisition, communication with any regulatory agency including, but not limited to, the FDA, or any business or competitive purpose or function, or (2) disclose or release to any person not authorized under this Order any PROTECTED INFORMATION received pursuant to this Order.

The recipient of any PROTECTED INFORMATION that is provided under this Order shall maintain such information in a secure and safe place and shall exercise reasonable care regarding the maintenance, storage, custody, and use of such information.

Nothing in this Order shall bar or otherwise restrict any Outside Counsel or Designated In-House Representative from rendering advice to his or her Party-client in this Action. Nothing in this Order shall bar or otherwise restrict such Party-client from relying upon such Outside Counsel's or Designated In-House Representative's examination and/or analysis of PROTECTED INFORMATION, provided, however, that in rendering such advice and in otherwise communicating with such client, such person shall not disclose any PROTECTED INFORMATION to unauthorized persons.

## 12. Patent Office, Business, and Regulatory Activities

Anyone having access to HIGHLY CONFIDENTIAL INFORMATION shall not engage except by leave of court, directly or indirectly, in

(i) any patent prosecution ~~Defendants' Proposed Addition:~~ on behalf of a party with the ability to propose new claims or claim amendments<sup>pl</sup> related to the subject matter of U.S. Patent Nos. 6,251,910; 6,525,060; 7,250,419; 7,265,124; 8,425,934; and any other patents or patent applications directed to ticagrelor or formulations containing ticagrelor, other than (a) to submit materials pursuant to 37 CFR 1.56 and (b) as required to provide notices related to litigation, *e.g.* under 21 C.F.R. § 314.107(f)(2),

~~Plaintiffs' Proposal~~ for the duration of these Actions (including any appeals) and for one year after final termination of these Actions (including any appeals); or<sup>e</sup>

~~Defendants' Proposal:~~ for the longer of: (a) duration of these Actions (including any appeals) and for one year after final termination of these Actions (including any appeals) or (b) the final abandonment or issuance of all divisionals, continuations, continuations-in-part, reissues or reexaminations from the Patents-in-Suit; or]

(ii) any counseling, litigation or other work before or involving the U.S. Food & Drug Administration ("FDA") or similar agency in a foreign country, including but not limited to the preparation and filing of ~~Plaintiff's Proposed Addition:~~ or responding to<sup>pl</sup> citizen petitions, that relates to the subject matter of U.S. Patent Nos. 6,251,910; 6,525,060; 7,250,419; 7,265,124; and 8,425,934, and any other patents or patent applications directed to ticagrelor or formulations containing ticagrelor, including regarding any New Drug Application or Abbreviated New Drug Application concerning ticagrelor,



but excluding such work concerning updating the FDA on the status of this Action or responding to the FDA regarding the receiving party's own NDA or ANDA or is directed toward obtaining or maintaining approval under such NDA or ANDA ~~[Defendants' Proposed Addition]~~, including advising the client or responding to inquiries concerning carve-outs, exclusivities or responding to citizen petitions<sup>u</sup>]; or

30A

(iii) making competitive business decisions concerning products containing ticagrelor.

~~[Plaintiffs' Proposal: For avoidance of doubt, prohibited "patent prosecution" does not include participation in reissue proceedings, reexamination proceedings, *inter partes* reviews, post grant reviews, or any other post-grant contested proceedings in the U.S. Patent & Trademark Office or any foreign patent office provided, however, that the person having access to HIGHLY CONFIDENTIAL INFORMATION may not amend, draft, or consult with counsel regarding the amendment of patent claims in such proceedings.]~~


30A

~~[Defendants' Proposal: For avoidance of doubt, prohibited "patent prosecution" as used herein includes representing the patentee in any proceedings in which new claims or claim amendments can be proposed during the proceeding, which may include reissue proceedings, reexamination proceedings, *inter partes* reviews, post grant reviews, or other contested proceedings in which the scope of existing claims is changed or new claims can be pursued in the U.S. Patent & Trademark Office or any foreign patent office.]~~

u

~~[Plaintiffs' Proposal: For avoidance of doubt, negotiating or executing an agreement settling litigation, including responsibilities related to any financial terms of such an agreement shall not be deemed to be related to any "competitive business decisions."]~~

30A

~~[Defendants' Proposal:~~ For avoidance of doubt, purely legal decision-making responsibilities relating to ticagrelor, including without limitation, for example, having responsibilities for negotiating or executing an agreement settling litigation, responsibilities related to any financial terms of such an agreement and responsibilities relating to advising about launch dates shall not be deemed to be related to any "competitive business decisions." An individual who merely provides legal advice regarding the development of ticagrelor products shall not be disqualified under this provision. 

**13. Manner of Identifying Produced Document**

Documents produced pursuant to discovery in this Action shall, where possible, bear a unique, per-page, identifying number, except unique identifying numbers are not required when documents are produced only for inspection.

**14. Manner of Designating PROTECTED INFORMATION**

a. Physical objects or documents containing CONFIDENTIAL INFORMATION shall be designated by stamping, marking, or affixing on each page or onto the physical object or its container thereto an identifying legend in the general form:

[party name] CONFIDENTIAL INFORMATION - SUBJECT TO PROTECTIVE ORDER

All correspondence, legal memoranda, motion papers, pleadings, and other written materials that quote or refer to the substance of any PROTECTED INFORMATION shall also be treated as PROTECTED INFORMATION in accordance with the provisions of this Order, and at least the cover or first page of such documents shall be marked according to this paragraph.

Physical objects or documents containing HIGHLY CONFIDENTIAL INFORMATION shall be designated by stamping, marking, or affixing on each page or onto the physical object or its container thereto an identifying legend in the general form:

[party name] HIGHLY CONFIDENTIAL INFORMATION - SUBJECT TO PROTECTIVE ORDER

In the event a receiving Party generates any paper printout, copy, image, or transcription from any designated physical object, such Party must stamp each page with the appropriate legend, and the paper printout or transcription shall be treated as PROTECTED INFORMATION.

b. PROTECTED INFORMATION revealed by inspection of things or premises shall be designated as “CONFIDENTIAL INFORMATION” or “HIGHLY CONFIDENTIAL INFORMATION” before the inspection by the Party or Third Party permitting inspection by specifying in writing the locations of and things which contain PROTECTED INFORMATION.

c. If documents are produced for inspection only, then all such documents will be treated as PROTECTED INFORMATION unless and until the producing party subsequently produces any such documents without a “CONFIDENTIAL INFORMATION” or “HIGHLY CONFIDENTIAL INFORMATION” designation. Such inspection, however, shall be conducted only by persons authorized under this Order to have access to HIGHLY CONFIDENTIAL INFORMATION.

d. Any party may designate any or all portions of depositions taken pursuant to this action as “CONFIDENTIAL INFORMATION” or “HIGHLY CONFIDENTIAL INFORMATION” either (1) by making a statement on the record at the deposition, or (2) by

serving notice in writing to counsel of record within thirty (30) days of receiving the transcript of the deposition. All deposition transcripts not previously designated shall be deemed to be and shall be treated as if designated “HIGHLY CONFIDENTIAL INFORMATION” for a period of up to thirty (30) days from receipt of the official transcript of the deposition by all parties to the deposition. A deponent may review the transcript of his or her deposition at any time.

e. A Party or Third Party that inadvertently fails to designate PROTECTED INFORMATION pursuant to this Order at the time of production shall be entitled to make a correction at any time. No showing of error, inadvertence, or excusable neglect shall be required for such correction. Such correction and notice thereof shall be made in writing, accompanied by substitute copies of each item, appropriately designated as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION. The Party receiving the PROTECTED INFORMATION before the notice and correction by the producing Party or Third Party shall return to Outside Counsel for the producing Party or Third Party all such previously undesignated PROTECTED INFORMATION with all copies, or certify destruction thereof, within five (5) business days after receiving the substitute copies. Upon receipt of correction and notice, the receiving Party shall honor the provisions of this Order and shall consider and treat as properly designated CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION the previously undesignated or improperly designated information. Under such circumstances, no receiving Party shall have any obligation or liability due to any disclosure of the PROTECTED INFORMATION that occurred before the receipt of correction and notice; provided, however, that any subsequent disclosure shall be in accordance with such corrected designation.

**15. *No Admission or Waiver***

Confidentiality designations are intended solely to facilitate compliance with discovery in this Action. Neither such designation nor treatment in conformity with such designation shall be construed as an admission or agreement by any Party or Third Party that the designated information constitutes or contains any trade secret or PROTECTED INFORMATION. Failure to so designate information shall not constitute a waiver of any claim by a Party or Third Party that information contains PROTECTED INFORMATION.

Nothing in this Order is intended as any representation that any (i) information, (ii) type or category of information, or (iii) type or category of documents is necessarily relevant to any issue in this litigation, or constitutes discoverable information. The parties reserve their rights to the production of documents that may fall within the scope of the definition of PROTECTED INFORMATION.

**16. *Treatment of PROTECTED INFORMATION***

Absent the consent of the producing Party, documents or information designated as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION shall be retained by the receiving or other counsel of any non-designating party and may be disclosed by any non-designating party only to:

(i) Outside Counsel of record for any Party to the Action, their staff, and any litigation service contractors whose function in connection with this Action requires access to such information including, for example, trial graphics personnel, contract attorneys, e-discovery vendors and consultants, translators, and photocopy services;



(ii) Designated In-House Representatives for the receiving Party who have signed the a Declaration of Acknowledgment and Agreement to be Bound by Protective Order (“Exhibit A”), consistent with the prohibition on HIGHLY CONFIDENTIAL INFORMATION of Paragraph 20 below, and their immediate staff, but only to the extent necessary to carry out duties related to this litigation;

(iii) any person agreed to in writing by the producing Party;

(iv) outside experts and consultants for any Party to the Action who meet the requirements of Paragraph 19 below and who have executed the Confidentiality Undertaking (Exhibit A), but only to the extent necessary to carry out duties related to this litigation;


(v) stenographers, court reporters, videographers or other individuals solely involved for the recordation and transcription of deposition or court proceedings or for like purposes at the request and consent of the parties; and

(vi) the Court, its staff, and designees.

~~[Plaintiffs’ Proposal: Nothing herein shall prevent one Party from using another Party’s PROTECTED INFORMATION on issues common to the consolidated Action in order to avoid burdening the Court with unnecessary subpoenas on a Party already of record in the litigation.]~~

RGA

~~[Defendants’ Proposal:~~ For avoidance of doubt, absent written consent from the producing party, Plaintiffs may not produce or otherwise make available one Defendant’s PROTECTED INFORMATION to any other Defendant. Furthermore, Plaintiffs may not use PROTECTED INFORMATION produced by one Defendant to support Plaintiffs’ claims or defenses against any other Defendant. Plaintiffs also may not use PROTECTED INFORMATION produced by one Defendant during fact deposition or cross-examination of another Defendant. To the extent a party contends that certain documents should be made

available to another party in the case, the parties agree to make good-faith efforts to address such situations on a case-by-case basis and resolve the issue. 

**17. *Actions to be taken in the event of unauthorized disclosure of PROTECTED INFORMATION***

If PROTECTED INFORMATION is disclosed to an unauthorized person or in a manner not authorized by this Order, the Party responsible for the unauthorized disclosure shall immediately upon learning of the unauthorized disclosure provide all pertinent facts relating to such disclosure (including the name(s) of the person(s) to whom disclosed) to the attention of the Outside Counsel for the designating Party or Third Party, without prejudice to other rights and remedies of the designating Party or Third Party. The Party responsible for the unauthorized disclosure shall use its best efforts to prevent further unauthorized use or disclosure of PROTECTED INFORMATION, shall use its best efforts to immediately retrieve all copies of the PROTECTED INFORMATION, and otherwise mitigate harm.

**18. *Additional Permissible Disclosure of PROTECTED INFORMATION***

Documents designated PROTECTED INFORMATION also may be disclosed and used during a deposition or at trial, subject to appropriate safeguards necessary to protect sensitive information contained in the documents, to: (i) persons listed on the face of the documents; (ii) persons otherwise shown to be the originator, author, or a recipient of such documents; or (iii) persons shown to have knowledge of the PROTECTED INFORMATION contained in the documents; or (iv) present employees, agents, and representatives of the designating Party or Third Party, its subsidiaries, or affiliates. Nothing in this Paragraph shall prevent a Party or a

Third Party from giving its consent to having its PROTECTED INFORMATION disclosed to any witness during a deposition or at trial.

**19. Access to PROTECTED INFORMATION by Outside Experts and Consultants**

As specified in Paragraph 16 above, outside experts or outside consultants and their staff whose advice and consultation are being or will be used in preparation for and/or at trial of this Action may have access to documents and information designated as PROTECTED INFORMATION pursuant to the following procedure:

a. Each such outside expert or consultant shall read this Order and execute a Confidentiality Agreement in the form attached hereto as Exhibit A before obtaining access to any PROTECTED INFORMATION.

b. Each such Confidentiality Agreement executed by a Party's expert(s) or consultant(s), along with a current copy of the expert's or consultant's curriculum vitae, a list of each expert or consultant's publications for the preceding ten (10) years, and a list of each expert or consultant's trial and/or deposition testimony given in the preceding four (4) years shall be transmitted to Outside Counsel for the Party from which the PROTECTED INFORMATION was obtained at least five (5) business days before the disclosure of any PROTECTED INFORMATION.

c. If a Party believes that disclosure of its PROTECTED INFORMATION to another Party's expert(s) or consultant(s) would injure or prejudice it, the Party may object in writing within five (5) business days of receipt of the materials described in Paragraph 19(b) above. If timely objection is made, the parties shall attempt in good faith to resolve the disclosure



issue. If the parties cannot resolve a dispute regarding disclosure to an outside expert or consultant, the objecting Party may apply to the Court for an order prohibiting disclosure of its PROTECTED INFORMATION to the outside expert or consultant. The objecting Party has ten (10) business days from receipt of the materials described in Paragraph 19(b) above to move the Court to preclude the outside expert or consultant from viewing its PROTECTED INFORMATION. If the objecting Party does not timely object and bring a timely motion, PROTECTED INFORMATION may be disclosed to the outside expert or consultant.

## **20. *Designated In-House Representatives***

(a) Each Party may designate up to two Designated In-House Representatives, as provided in Paragraphs 10 and 16, above, by providing notice to the other parties along with a signed Declaration of Acknowledgment and Agreement to be Bound by Protective Order annexed as Exhibit A from each such Designee. The notice shall include the employee's name, description of the employee's position(s), title(s), and responsibilities for the past five years. A Designated In-House Representative may be replaced by substitute Designated In-House Representative upon notification regarding the substitution.

(b) Material designated as HIGHLY CONFIDENTIAL INFORMATION shall not be disclosed to any Designated In-House Representative without prior written agreement of the designating Party or Third Party or by Order of the Court. With respect to any expert report served in this action, and any pleading, brief or other paper filed with the Court or served on the Parties in this action that contains or refers to any HIGHLY CONFIDENTIAL INFORMATION of a Party, and upon request, the producing Party whose HIGHLY CONFIDENTIAL INFORMATION is disclosed therein shall provide to the receiving party a redacted version

within three (3) business days of filing or service for disclosure to the Designated In-House Representatives of such receiving party who are qualified recipients of CONFIDENTIAL INFORMATION under the terms of Section 16(ii). This redacted version shall only redact such HIGHLY CONFIDENTIAL INFORMATION as that term is defined in this Order, the disclosure of which is highly likely to cause significant harm to an individual or to the business or competitive position of the producing Party. In the event that the receiving party believes that any information redacted pursuant to this Paragraph can appropriately be disclosed to the Designated In-House Representatives, the Parties shall meet and confer to address such concerns and bring the matter to the Court's attention if required.

(c) If a Party believes that disclosure of its PROTECTED INFORMATION to a Party's Designated In-House Representative would injure or prejudice it, the Party may object in writing within five (5) business days of receiving notice of the designation from the designating Party pursuant to paragraph (a) above. If timely objection is made, the parties shall attempt in good faith to resolve the disclosure issue. If the parties cannot resolve a dispute regarding disclosure to a Designated In-House Representative, the objecting Party may apply to the Court for an order prohibiting disclosure of its PROTECTED INFORMATION to the Designated In-House Representative. The objecting Party has fifteen (15) business days from receipt of the notice of the designation from the designating Party pursuant to paragraph (a) above to move the Court to preclude the Designated In-House Representative from viewing its PROTECTED INFORMATION. If the objecting Party does not timely object or bring a timely motion, PROTECTED INFORMATION may be disclosed to the Designated In-House Representative.

## **21. *Effect of this Order on Discovery***

This Order shall not preclude or limit the right of any Party or Third Party to oppose discovery on any ground which would otherwise be available.

**22. *Inadvertent Production and Non-Waiver of Privileges***

Pursuant to Federal Rule of Evidence 502, inadvertent production in the course of discovery of any information, in any form (whether properly designated as PROTECTED INFORMATION or not) shall not waive any privilege or immunity that would otherwise attach to the information produced, provided that the producing Party or Third Party notifies the Outside Counsel for the receiving Party of the claim of privilege or immunity within seven (7) business days after discovery of the inadvertent production. Upon such notice, the receiving Party and Outside Counsel for the receiving Party shall return to the producing Party or Third Party all documents and things containing information claimed to be subject to any privilege or immunity along with any notes or summaries referring or relating to those documents and things, or certify destruction thereof, within ten (10) business days, except that where the receiving Party submits a motion, or other request, with the Court within ten (10) business days challenging the claim of privilege or immunity, return or destruction may be postponed until the date upon which such motion or request is resolved. The receiving Party, however, shall not use or rely upon any information produced and claimed to be subject to any privilege or immunity during the pendency of any motion or request challenging such claim. Returning or destroying inadvertently produced materials shall not constitute an acknowledgment that the information contained in the materials is privileged or immune from discovery.

Notwithstanding the provisions of the preceding paragraph, if any document or information is:

- a. marked as an exhibit in a deposition at which the producing Party is represented by counsel;
- b. presented as an exhibit to, or specifically identified in, any brief, legal memorandum, affidavit or declaration filed and/or served in this Action;
- c. presented as an exhibit to, or specifically identified in any expert report served in this Action;
- d. specifically identified in an interrogatory answer or other discovery response (or section of the Pretrial Order) served by the Producing Party in this Action; or
- e. specifically identified at any hearing in this Action by any Party;

then the Producing Party will be entitled to relief under this Paragraph only if the Producing Party makes a claim of inadvertent production under this Paragraph within seven (7) business days after such use or identification of the document or information.

Nothing in this Protective Order shall preclude the receiving Party returning or destroying inadvertently produced material from seeking an order compelling the production of information previously produced inadvertently.

### **23. *Effect of this Order on Depositions***

Consistent with Paragraph 18 above and all other provisions of this Order, when a Party's or Third Party's CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION is discussed or disclosed during a deposition, the Party or Third Party may exclude any person not authorized under this Order to have access to the CONFIDENTIAL

INFORMATION or HIGHLY CONFIDENTIAL INFORMATION from the deposition while the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION is disclosed or discussed.

**24. *Discovery Requests Received from Third Parties***

In the event that a producing Party's PROTECTED INFORMATION is sought from a receiving Party or Third Party, by subpoena, by service with any legal process, by order, or otherwise, prompt written notice shall be given to the party who produced the PROTECTED INFORMATION to allow this Party to object to the production of such PROTECTED INFORMATION. Notice shall include a copy of such subpoena, legal process, or order. If the Party that produced the PROTECTED INFORMATION does not object to the disclosure of PROTECTED INFORMATION within ten (10) business days of receiving notice then the Party to whom the referenced subpoena is directed may produce such documents in response thereto. Any Third Party seeking such PROTECTED INFORMATION who takes action to enforce such subpoena or other legal process shall be apprised of this Order by the Party from whom the PROTECTED INFORMATION is sought. Nothing herein shall be construed as requiring anyone covered by this Order to contest a subpoena or other process, to appeal any order requiring production of PROTECTED INFORMATION covered by this Order, or to subject itself to penalties for non-compliance with any subpoena, legal process, or order.

**25. *Discoverability of Expert Materials***

Discovery of communications between counsel and any independent expert or consultant retained or specially employed by that counsel shall be limited to factual information, analyses,

documents, and data relied on by the expert in rendering the opinions expressed in an expert report or at trial. Except as otherwise provided herein, all other communications between counsel and the expert relating to the process of preparing an expert report or developing opinions for trial, including all preliminary or draft reports, expert working papers, notes, and communications relating thereto, shall be deemed exempt from discovery and use at trial.

**26. *Other Proceedings***

By entering this Order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or Party subject to this Order who becomes subject to a motion to disclose another Party's or Third Party's information designated PROTECTED INFORMATION pursuant to this Order shall promptly notify that Party of the motion so that the party may have an opportunity to appear and be heard on whether the information should be disclosed.

**27. *Modification and Additional Protective Orders***

Nothing herein shall prevent any Party from: (i) applying to the Court for a modification of this Order; (ii) applying to the Court for further or additional protective orders; or (iii) making an agreement with other parties in this Action to modify this Order, subject to Court approval.

**28. *Motion for Relief From PROTECTED INFORMATION Designation***

A Party shall not be obligated to challenge the propriety of a PROTECTED INFORMATION designation at the time made, and failure to do so shall not preclude a

subsequent challenge during the pendency of the litigation. A Party challenging a designation shall provide written notice to the Party or Third Party who produced the PROTECTED INFORMATION.

Upon motion, the Court may affirm the appropriateness of the confidentiality designation or order its removal from any information so designated. Regarding any motion concerning the propriety of a confidentiality designation, the Party or Third Party making the designation shall bear the burden of proof.

**29. *Filing Documents Designated as PROTECTED INFORMATION with the Court***

If a Party wishes to file or lodge with the Court for any purpose any document, transcript, or thing containing PROTECTED INFORMATION, the Party shall designate the material as PROTECTED INFORMATION as set forth in Paragraph 14 above, and it shall be filed under seal in accordance with the provisions of the United States District Court for the District of Delaware’s Revised Administrative Procedures Governing Filing and Service by Electronic Means dated October 16, 2014 (“the Procedures”). All such documents so filed shall be released from confidential treatment by the Court only upon further order of the Court. In addition, courtesy paper copies of sealed documents shall be filed with the Clerk’s office as provided in Section (G)(1) of the Procedures and shall be in a sealed envelope bearing the caption of the case and the confidentiality designation.

If a Party files or lodges with the Court any document, transcription, or thing containing information containing PROTECTED INFORMATION, the Party shall comply with the provisions of Section (G) of the Procedures, including without limitation the provisions

governing the filing of a redacted version of the sealed document for public inspection within seven (7) calendar days.

Upon the failure of the filing or lodging Party to properly designate information in accordance with its confidentiality designation, any Party or Third Party who in good faith believes that designation and filing under seal is required may move the Court to file said information under seal within ten (10) business days of learning of the defective filing or lodging. Notice of such designation shall be given to all parties in this Action. Nothing in this provision relieves a Party of liability for damages caused by failure to properly file PROTECTED INFORMATION under seal. The burden of proving that such information should be sealed shall at all times remain on the party which designated the information.

### **30. *Order Binding Date***

The parties agree that upon execution by the parties, it will be treated as though it has been “So Ordered.” Nothing in this Paragraph is intended to alter the provisions of Local Rule 26.2 of this Court or any prior agreement by a receiving party concerning the use of documents produced in this litigation under Local Rule 26.2.

### **31. *Conclusion of Litigation***

At the conclusion of the Action, by judgment or otherwise, including all appeals, all documents and information designated in the Action as PROTECTED INFORMATION, including electronic copies thereof, shall be, at the receiving Party’s election, either (1) returned within thirty (30) calendar days of the conclusion of the litigation after the later of a final judgment herein, the mandate has issued in the case of an appeal, or settlement of this Action to



the producing Party or Third Party along with all copies thereof, or (2) destroyed within thirty (30) calendar days after the later of a final judgment herein, the mandate has issued in the case of an appeal, or settlement of this Action by the receiving Party, after which the receiving Party will certify within forty-five (45) calendar days of the conclusion of the Action that such return and/or destruction has in fact been completed. At the conclusion of the Action, all documents prepared in the Action by attorneys (including Outside Counsel and Designated In-House Counsel), and outside experts and consultants designated pursuant to Paragraph 13 above, containing summaries, abstracts, or quotations from documents designated by a Party or Third Party as protected by this Order, shall be destroyed within thirty (30) calendar days or kept within the internal files of the Outside Counsel for the Party creating such documents.

Any legal briefs or memoranda containing PROTECTED INFORMATION prepared by Outside Counsel of any Party may be retained in the Outside Counsel's internal files. Outside Counsel may retain all documents and things that contain or reflect their attorney work product (e.g., notes, memoranda, drafts of pleadings, deposition summaries, document review summaries, documents reviewed in preparation for depositions, hearings, or trial, whether introduced or not), one copy of all correspondence, all pleadings, all deposition transcripts, all expert reports, all exhibits to depositions and expert reports, all hearing and trial transcripts, all hearing and trial exhibits, and all court-filed documents even though they contain PROTECTED INFORMATION, but such retained work product and documents shall remain subject to the terms of this Order. In the event that Outside Counsel maintains such documents, it shall not disclose material containing any type of PROTECTED INFORMATION to another party absent subpoena or court order. Upon receipt of any subpoena for such information, the Party receiving

the subpoena shall immediately notify Outside Counsel for the producing Party of the subpoena so that the latter may protect its interests.

**32. *Survival of Terms of this Order***

The provisions of the Order shall survive the final termination of the Action for any retained information, documents and contents thereof.

**33. *New Parties***

In the event that a new Party is added or substituted, this Order will be binding on the new Party, subject to the right of the new Party to seek relief from the Court for modification of this Protective Order.

**AGREED TO:**

DATED: \_\_\_\_\_, 2016

MCCARTER & ENGLISH, L.L.P.

YOUNG CONAWAY STARGATT &  
TAYLOR, L.L.P.

\_\_\_\_\_  
Michael P. Kelly (#2295)  
Daniel M. Silver (#4758)  
Benjamin A. Smyth (#5528)  
Renaissance Centre  
405 N. King Street, 8th Floor  
Wilmington, Delaware 19801  
(302) 984-6300  
mkelly@mccarter.com  
dsilver@mccarter.com  
bsmyth@mccarter.com

*Attorneys for Plaintiffs AstraZeneca AB,  
AstraZeneca Pharmaceuticals LP,  
AstraZeneca UK Limited, and AstraZeneca  
LP*

\_\_\_\_\_  
James M. Lennon (No. 4570)  
Gregory J. Brodzik (No. 5722)  
Rodney Square  
1000 North King Street  
Wilmington, DE 19801  
(302) 571-6600  
jlennon@ycst.com  
gbrodzik@ycst.com

*Attorneys for Defendant Mylan  
Pharmaceuticals Inc.*

CAESAR RIVISE, P.C.

BAYARD, P.A.

---

R Touhey Myer (#5939)  
800 N. King Street – Suite 304  
Wilmington, DE 19801  
Tel: (302) 544-9100  
tmyer@crbcp.com

*Attorneys for Defendants  
InvaGen Pharmaceuticals, Inc. and  
Sigmapharm Laboratories, LLC*

---

Richard D. Kirk (rk0922)  
Stephen B. Brauerman (sb4952)  
Vanessa R. Tiradentes (vt5398)  
Sara E. Bussiere (sb5725)  
222 Delaware Avenue, Suite 900  
Wilmington, DE 19899  
(302) 655-5000  
rkirk@bayardlaw.com  
sbrauerman@bayardlaw.com  
vtiradentes@bayardlaw.com  
sbussiere@bayardlaw.com

*Attorneys for Defendants HEC Pharm Co.,  
Ltd. and HEC Pharm USA, Inc.*

YOUNG CONAWAY STARGATT & TAYLOR  
L.L.P.

RICHARDS, LAYTON & FINGER, P.A.

---

Karen L. Pascale (#2903)  
Anne Shea Gaza (#4093)  
Robert M. Vrana (# 5666)  
Rodney Square  
1000 North King Street  
Wilmington, DE 19801  
(302) 571-6600  
kpascale@ycst.com  
agaza@ycst.com  
rvrana@ycst.com

*Attorneys for Defendants Amneal  
Pharmaceuticals LLC, and Amneal  
Pharmaceuticals of New York,  
LLC*

---

Kelly E. Farnan (#4395)  
Christine Dealey Haynes  
One Rodney Square  
920 N. King Street  
Wilmington, Delaware 19801  
302-651-7700  
Farnan@rlf.com  
Haynes@rlf.com

*Attorneys for Defendant Princeton  
Pharmaceutical Inc.*

COZEN O'CONNOR P.C.

POTTER ANDERSON & CORROON LLP

---

Joseph J. Bellew (#4816)  
1201 N. Market Street, Suite 1001  
Wilmington, DE 19801  
Tel: (302) 295-2025  
Fax: (215) 701-2431  
jbellew@cozen.com

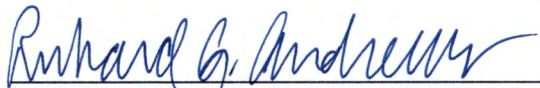
*Attorneys for Defendants  
Apotex Inc. and Apotex Corp.*

---

David E. Moore (#3983)  
Bindu A. Palapura (#5370)  
Stephanie E. O'Byrne (#4446)  
Hercules Plaza, 6<sup>th</sup> Floor  
1313 N. Market Street  
Wilmington, DE 19801  
Tel: (302) 984-6000  
dmoore@potteranderson.com  
bpalapura@potteranderson.com  
sobyne@potteranderson.com

*Attorneys for Defendant Watson Laboratories, Inc.*

SO ORDERED THIS 25<sup>th</sup> DAY OF April 2016



UNITED STATES DISTRICT COURT JUDGE

**EXHIBIT A**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

ASTRAZENECA LP, ASTRAZENECA AB,  
ASTRAZENECA UK LIMITED, and  
ASTRAZENECA PHARMACEUTICALS LP,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

Civil Action No.: 15-1000-RGA  
(CONSOLIDATED)

**“EXHIBIT A” TO STIPULATED PROTECTIVE ORDER**

**I. DECLARATION OF ACKNOWLEDGMENT AND AGREEMENT TO BE  
BOUND BY PROTECTIVE ORDER**

I, \_\_\_\_\_, declare under penalty of perjury under  
the laws of the United States that:

1. My present employer is \_\_\_\_\_ and its address  
is \_\_\_\_\_.

2. My present occupation or job description is \_\_\_\_\_.

3. I hereby certify that I have read and understand the terms of the Stipulated  
Protective Order (“Protective Order”) among the parties in consolidated C.A. No. 15-1000-RGA.

4. I agree that I will not use, disclose, or allow to be disclosed to anyone not  
expressly permitted by the Protective Order to receive PROTECTED INFORMATION, any of  
the contents of PROTECTED INFORMATION received under protection of the Protective  
Order. I also agree to be bound by the terms and conditions of the Protective Order.

5. I agree that, as to all individuals not expressly permitted to receive PROTECTED INFORMATION, I am to keep confidential all copies of any materials that I receive, whether at home or at work, which have been designated as PROTECTED INFORMATION. I also agree that I will carefully maintain such materials in a container, drawer, room, or other safe place in a manner consistent with the Protective Order, and that I will return or destroy such materials in a manner consistent with the Protective Order. I acknowledge that such return or the subsequent destruction of such materials shall not relieve me from any of the continuing obligations imposed upon me by the Protective Order.

6. For the purpose of enforcement of the Protective Order, I hereby submit to the jurisdiction of United States District Court for the District of Delaware.

DATED: \_\_\_\_\_  
\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Printed Name)

# EXHIBIT 3



**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

ASTELLAS PHARMA INC., ASTELLAS )  
IRELAND CO., LTD., and ASTELLAS )  
PHARMA GLOBAL DEVELOPMENT, )  
INC., )

Plaintiffs, )

v. )

ACTAVIS ELIZABETH LLC, et al., )

Defendants. )

Civil Action No. 16-905-SLR-CJB  
CONSOLIDATED

**MEMORANDUM ORDER**

At Wilmington this **20th day of July, 2017**.

**WHEREAS**, on July 19, 2017 the Court held a teleconference regarding protective order disputes between Plaintiffs Astellas Pharma Inc., Astellas Ireland Co., Ltd., and Astellas Pharma Global Development, Inc. (collectively, “Plaintiffs”), and Defendants Actavis Elizabeth LLC, Lupin Ltd., Lupin Pharmaceuticals, Inc., Zydus Pharmaceuticals (USA), Inc., Cadila Healthcare Ltd. (d/b/a Zydus Cadila), Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc., Aurolife Pharma LLC, Princeton Pharmaceutical Inc., Sawai Pharmaceutical Co., Ltd., Sawai USA, Inc., Sandoz, Inc., Apotex Inc. and Apotex Corp. (collectively, “Defendants”)<sup>1</sup>;

**NOW, THEREFORE, IT IS HEREBY ORDERED** that:

1. As to the parties’ first dispute, which relates to production of non-party confidential information pursuant to the Protective Order, the Court will ADOPT Plaintiffs’

---

<sup>1</sup> Plaintiffs and Defendant Windlas Healthcare Pvt. Ltd. (“Windlas”) are bound by the Stipulation and Order to Stay Claims and Be Bound By Result in Litigation, dated July 11, 2017. (D.I. 60; *see also* D.I. 61 at 1 n.1) Windlas did not participate in the teleconference.

proposed language. (*See* D.I. 61, ex. 1 at ¶ 3)<sup>2</sup> This dispute is really about the process by which confidential third-party information that is in Defendants' possession will be disclosed or withheld, and the burdens associated with the process for producing or withholding such information. The Court finds that Plaintiffs' proposal best accomplishes the goals of facilitating the efficient flow of discovery, while also providing a full and fair mechanism for non-parties to intervene and object to the disclosure of their confidential information.

2. The parties' second dispute relates to the disclosure of Plaintiffs' confidential information between Defendants. As to this dispute, the Court will again ADOPT Plaintiffs' proposed language. (*See id.* at ¶ 10) That language specifies that the proposed restrictions shall apply only to confidential information "that relates *solely* to the validity, enforceability or infringement of [United States] Patent No. 6,346,532 (the '532 patent)[.]" (*Id.* (emphasis added)) It is not disputed that if Plaintiffs possess records that do in fact relate *solely* to the validity, enforceability or infringement of the '532 patent, then the Defendant Groups that are not asserting that the '532 patent is invalid, unenforceable, and/or not infringed would have no right to such documents under Federal Rule of Civil Procedure 26, since the records would not be "relevant to any [of those Defendant Group's] claim[s] or defense[s]." Fed. R. Civ. P. 26(b). And the Court finds that Plaintiffs' proposal provides the best way for the parties to identify and tee up with the Court any disputes about whether a record falls into this category, and whether it may be shared with certain other Defendants.

3. With regard to the parties' third dispute, which relates to the disclosure by

---

<sup>2</sup> The parties shall change the phrase "the Court shall order production of" in Plaintiffs' proposal to "the Producing Party shall produce[.]"

Plaintiffs of Defendants' confidential information between other Defendants, the Court will ADOPT Defendants' proposed language. (*See* D.I. 61, ex. 1 at ¶ 10) In balancing here between the competing interests of (1) litigation-related efficiency and (2) protecting the parties' confidential information, the Court errs on the side of the latter. The Court notes that Defendants' proposed language is consistent with other Protective Orders in ANDA cases within this District. *See, e.g., AstraZeneca LP v. Sigmapharm Labs., LLC*, Civil Action No. 15-1000-RGA (D. Del. Apr. 26, 2016) (D.I. 71 at ¶ 16); *Forest Labs., LLC v. Apotex Corp.*, Civil Action No. 15-18-GMS (D. Del. Sept. 18, 2015) (D.I. 48 at ¶ 19).

4. As to the parties' final dispute, which concerns participation in post-grant proceedings by those with access to confidential information, the Court will ADOPT Plaintiffs' proposed language, and DENY Defendants' request to preclude Plaintiffs' trial counsel from "providing recommendations regarding drafting, crafting, or amending of patent claims" in any post-grant proceedings with respect to patents involving mirabegron. (D.I. 61, ex. 1 at ¶ 10(A)) In adjudicating disputes over what kind of prosecution bar should be entered, the Court must balance (1) any unacceptable risk of inadvertent disclosure or competitive use of confidential information against (2) the potential harm the party affected by the portion of the bar at issue would face were that portion adopted, and were it denied its counsel of choice. *See Toshiba Samsung Storage Tech. Korea Corp. v. LG Elecs., Inc.*, Civil Action No. 15-691-LPS-CJB, 2016 WL 447794, at \*1 (D. Del. Feb. 4, 2016) (hereinafter, "*TSST-K*") (citing *In re Deutsche Bank Trust Co. Ams.*, 605 F.3d 1373, 1379-80 (Fed. Cir. 2010)). It is Defendants' burden to show good cause for its proposed provision effecting a prosecution bar. *See, e.g., id.* at 1 n.1; *Xerox Corp. v. Google, Inc.*, 270 F.R.D. 182, 183-84 (D. Del. 2010). And here, there is very little

concrete evidence in the record regarding either (1) the risk of inadvertent disclosure or competitive use of confidential information, or (2) the potential harm that Plaintiffs would suffer were they to be denied the counsel of their choice. The Court is also cognizant that “it is hard to dispute that the magnitude of [the risk of inadvertent disclosure of or competitive use of confidential information] is far less pronounced with respect to an IPR proceeding (in which [the patentee’s] claims may be only narrowed, not enlarged) as compared to the prosecution of a new patent[.]” *TSST-K*, 2016 WL 447794, at \*2 (citations omitted). In light of this, and the lack of record evidence on the issue, the Court finds that Defendants have not met their burden here. However, the Court will consider a request to modify the Protective Order in the future as to this issue, if the evidence warrants it. *Cf. Boston Scientific Corp. v. Cook Group Inc.*, Civil Action No. 15-980-LPS-CJB (D. Del. Apr. 18, 2016) (D.I. 36 at ¶ 9).

5. The parties are ORDERED to submit a final proposed Protective Order, incorporating the above decisions, by no later than **July 27, 2017**.



Christopher J. Burke  
UNITED STATES MAGISTRATE JUDGE

# EXHIBIT 4

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

- - -

NOVARTIS PHARMACEUTICALS  
CORPORATION,

: CIVIL ACTION

Plaintiff,

v

APOTEX INC. and APOTEX CORP.,

Defendants.

: NO. 18-1038-LPS

-----  
NOVARTIS PHARMACEUTICALS  
CORPORATION,

: CIVIL ACTION NO.

Plaintiff,

v

TEVA PHARMACEUTICALS USA, INC. and  
ACTAVIS ELIZABETH LLC,

Defendants.

: 18-1039-LPS

-----  
NOVARTIS PHARMACEUTICALS  
CORPORATION,

: CIVIL ACTION

Plaintiff,

v

SUN PHARMACEUTICAL INDUSTRIES LTD,  
et al.,

Defendants.

: NO. 18-1040-LPS

- - -

Wilmington, Delaware

Tuesday, October 16, 2018

*Discovery and Scheduling Telephone Conference*

- - -

BEFORE: HONORABLE LEONARD P. STARK, Chief Judge

- - -

(Captions continued on Page 2)

Brian P. Gaffigan  
Official Court Reporter

-----  
 NOVARTIS PHARMACEUTICALS :  
 CORPORATION, : CIVIL ACTION  
 :  
 Plaintiff, :  
 v :  
 :  
 ACCORD HEALTHCARE, INC., LTD, et al., :  
 :  
 Defendants. : NO. 18-1043-LPS  
 -----

APPEARANCES:

McCARTER & ENGLISH, LLP  
 BY: BENJAMIN A. SMYTH, ESQ.

and

GIBSON, DUNN & CRUTCHER, LLP  
 BY: JANE LOVE, Ph.D., ESQ., and  
 ROBERT TRENCHARD, ESQ.

and

GIBSON, DUNN & CRUTCHER, LLP  
 BY: ANDREW P. BLYTHE, ESQ.

Counsel for Novartis Pharmaceuticals  
 Corporation

PHILLIPS GOLDMAN McLAUGHLIN & HALL, P.A.  
 BY: JOHN C. PHILLIPS, JR., ESQ., and  
 MEGAN C. HANEY, ESQ.

and

LOCKE LORD, LLP  
 BY: DAVID B. ABRAMOWITZ, ESQ.

Counsel for Zydus Pharmaceuticals (USA) Inc.  
 and Cadila Healthcare Limited

1 APPEARANCES: (Continued)

2 YOUNG CONAWAY STARGATT & TAYLOR, LLP  
3 BY: ADAM WYATT POFF, ESQ.

4 and

5 KNOBBE MARTENS OLSON & BEAR, LLP  
6 BY: BENJAMIN A. KATZENELLENBOGEN, ESQ.

7 Counsel for Glenmark Pharmaceuticals Inc.  
8 USA, and Glenmark Pharmaceuticals Limited

9 SMITH, KATZENSTEIN & JENKINS, LLP  
10 BY: KATHLEEN MILLER, ESQ.

11 and

12 BUDD LARNER, P.C.  
13 BY: LOUIS H. WEINSTEIN, ESQ.

14 Counsel for Accord Healthcare, Inc.,  
15 Dr. Reddy's Laboratories, Ltd., Dr. Reddy's  
16 Laboratories, Inc., Torrent Pharma Inc.,  
17 and Torrent Pharmaceuticals Ltd.

18 SHAW KELLER, LLP  
19 BY: DAVID FRY, ESQ.

20 and

21 KIRKLAND & ELLIS, LLP  
22 BY: AMANDA J. HOLLIS, ESQ., and  
23 SARA TSOU, ESQ.

24 Counsel for Teva Pharmaceuticals USA, Inc.,  
25 and Actavis Elizabeth LLC

MORRIS JAMES, LLP  
BY: KENNETH L. DORSNEY, ESQ.

and

TAFT STETTINIUS  
BY: STEPHEN R. AUTEN, ESQ.

Counsel for Alkem Laboratories Ltd.



1 APPEARANCES: (Continued)

2  
3 POTTER ANDERSON & CORROON, LLP  
4 BY: JENNIFER P. BUCKLEY, ESQ.

5 and

6 WILSON SONSINI GOODRICH & ROSATI  
7 BY: TUNG-ON KONG, ESQ., and  
8 DENNIS D. GREGORY, ESQ.

9 Counsel for Apotex Inc. and Apotex Corp.

10 MORRIS JAMES, LLP  
11 BY: KENNETH L. DORSNEY, ESQ.

12 and

13 KRATZ & BARRY  
14 BY: GEORGE J. BARRY, III, ESQ.

15 Counsel for Aurobindo Pharma Limited and  
16 Aurobindo Pharma USA, Inc.

17 PHILLIPS GOLDMAN McLAUGHLIN & HALL, P.A.  
18 BY: JOHN C. PHILLIPS, JR., ESQ., and  
19 MEGAN C. HANEY, ESQ.

20 and

21 KATTEN MUCHIN & ROSENMAN, LLP  
22 BY: KIMBERLY A. BEIS, ESQ.

23 Counsel for Biocon Limited  
24 and Biocon Pharma, Inc.

25 MORRIS JAMES, LLP  
BY: KENNETH L. DORSNEY, ESQ.

and

HOLLAND & KNIGHT  
BY: HOWARD S. SUH, ESQ.

Counsel for Bionpharma Inc., Hetero USA Inc.,  
Hetero Labs Limited Unit-V, and Princeton  
Pharmaceuticals, Inc.

1 APPEARANCES: (Continued)

2 RICHARDS LAYTON & FINGER, P.A.  
3 BY: KELLY E. FARNAN, ESQ., and  
4 SARA METZLER, ESQ.

5 and

6 BRECKENRIDGE PHARMACEUTICAL INC.  
7 BY: ROBERT VROOM, ESQ.

8 Counsel for Breckenridge Pharmaceutical Inc.

9 PHILLIPS GOLDMAN McLAUGHLIN & HALL, P.A.  
10 BY: JOHN C. PHILLIPS, JR., ESQ., and  
11 MEGAN C. HANEY, ESQ.

12 and

13 GOODWIN PROCTER, LLP  
14 BY: CINDY CHANG, ESQ.

15 Counsel for Emcure Pharmaceuticals and  
16 Heritage Pharmaceuticals Inc.

17 STAMOULIS & WEINBLATT, LLC  
18 BY: STAMATIOS STAMOULIS, ESQ.

19 and

20 McANDREWS HELD & MALLOY LTD.  
21 BY: AARON F. BARKOFF, ESQ.

22 Counsel for Ezra Ventures, LLC

23 STAMOULIS & WEINBLATT, LLC  
24 BY: STAMATIOS STAMOULIS, ESQ.

25 and

SKIERMONT DERBY, LLP  
BY: STEVEN J. UDICK, ESQ.

Counsel for HEC Pharm Co., Ltd.  
and HEC Pharm USA Inc.

1 APPEARANCES: (Continued)

2 FINGER & SLANINA, LLC  
3 BY: DAVID L. FINGER, ESQ.

4 and

5 MARTON RIBERA SCHUMANN & CHANG  
6 BY: DAVID J. AUSTIN, ESQ.

7 Counsel for MSN Laboratories Private Limited,  
8 MSN Pharmaceuticals Inc., Nostrum Laboratories  
9 Inc. and Nostrum Pharmaceuticals, LLC

10 RICHARDS LAYTON & FINGER, P.A.  
11 BY: ALEXANDRA M. EWING, ESQ.

12 and

13 PERKINS COIE, LLP  
14 BY: BRANDON M. WHITE, ESQ., and  
15 SHANNON M. BLOODWORTH, ESQ.

16 Counsel for Mylan Pharmaceuticals, Inc.

17 HEYMAN ENERIO GATTUSO & HIRZEL, LLP  
18 BY: JAIME L. BROWN, ESQ.

19 and

20 WINSTON & STRAWN, LLP  
21 BY: ZACHARY L. SORMAN, ESQ.

22 Counsel for Sun Pharmaceutical Industries Ltd.,  
23 Sun Pharmaceutical Industries, Inc., and Sun  
24 Pharma Global FZE  
25

1 paragraph 16, if plaintiffs come to believe there is a  
2 specific concern later on, they can raise that with us. And  
3 if we can't agree, we will go to Your Honor.

4 THE COURT: All right. Thank you.

5 So in the proposed protective order, and I will  
6 give you a week, so the same deadline as next, as the other,  
7 as the scheduling to get your revised submission in, in  
8 that proposal next week, I do authorize the inclusion of  
9 something along the lines of what the defendants have  
10 proposed in paragraph 16, but I have a little bit more  
11 guidance for you on that.

12 I'm more comfortable with something along the  
13 lines of the first sentence, the "without prior written  
14 approval, no party may disclose the protected information of  
15 any defendant to another defendant." I'm more comfortable  
16 with that than the second sentence which talks about "use"  
17 and "reliance" and "introducing into evidence," all of which  
18 strike me as concepts more relating to summary judgment if  
19 we were to have it and, more importantly, trial. I don't  
20 think in a protective order I should really be addressing  
21 what is going to happen at trial and what evidence could be  
22 admitted. We can evaluate all of that much better, much  
23 more concretely in and around the time of the pretrial  
24 conference when, among other things, we'll know which  
25 defendants are still here and are actually going to trial.

1           In addition, I think paragraph 16 needs to  
2 explicitly say something about a court order could, of  
3 course, modify this, and should expressly reference that  
4 the parties do need to meet and confer if the plaintiffs  
5 are making a request to have some particular exception  
6 from paragraph 16.

7           I think you all, with that guidance, can write  
8 language that will reasonably balance the competing  
9 interests here. It's always a difficult balance, but I  
10 don't think plaintiffs should be per se precluded with no  
11 ability to ask for an exception to use one defendant's  
12 information even against another.

13           On the other hand, the defendants I recognize  
14 are competitors with one another, and there is a real risk  
15 of competitive harm to their information falling into the  
16 hands of competitors, even outside counsel who might  
17 inadvertently misuse that in advising their own client.

18           It seems that this is not really going to be a  
19 ripe dispute until around the time expert reports are being  
20 prepared. The parties should be meeting and conferring on  
21 numerous issues between now and then, and plaintiffs  
22 reasonably should be able to see this coming. And so I  
23 don't think this is going to lead to an inordinate number of  
24 emergent disputes in front of me, and I certainly hope not.

25           I've got to run in a minute, but are there any

1       questions about that from plaintiff?

2                   MR. TRENCHARD:  No, Your Honor.  Thank you very  
3       much.

4                   THE COURT:  And from defendants?

5                   MR. KATZENELLENBOGEN:  No, Your Honor.  Thank  
6       you very much.

7                   THE COURT:  Thank you very much.  We'll look for  
8       your submissions next week.

9

10                   (Telephone conference ends at 4:07 p.m.)

11

12                   I hereby certify the foregoing is a true and accurate  
13       transcript from my stenographic notes in the proceeding.

14

15                               /s/ Brian P. Gaffigan  
16                               Official Court Reporter  
17                               U.S. District Court  
18  
19  
20  
21  
22  
23  
24  
25

# EXHIBIT 5

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

IN RE: FETZIMA

Civil Action No.

2:17-CV-10230-ES-SCM

**ORDER**

**THIS MATTER** having come before the Court by way of the parties' joint dispute letter (D.E. 59) regarding disputed language in the proposed discovery confidentiality order, and the Court having conducted a telephone conference on May 16, 2018, and having considered the parties' submissions, and for good cause shown;

**IT IS** on this Friday, May 18, 2018,

**ORDERED**, as follows:

1. Paragraph 13(b)--Access to Confidential Information; shall incorporate Plaintiffs' proposal with the revision "Or up to two (2) representatives employed by the party with responsibilities for managing this Proceeding, but only if a party does not have ~~any~~ in-house counsel with any responsibility over patent litigation (referred to hereinafter as "representatives").
2. Paragraph 14(b), (c), and (i)--Access to Highly Confidential Information; shall incorporate Defendants' proposal, but with the modified language from ¶ 13(b). Accordingly, a party may only designate representatives if they do not have in-house counsel with responsibility over patent litigation.
3. Paragraph 15--Attendance at depositions; shall incorporate Defendant MSN's proposal.
4. Paragraph 16--Limitations on examination at a deposition, hearing, or trial; shall incorporate Plaintiffs' proposal with the revision "Confidential or Highly Confidential information that the witness authored, received, previously accessed, had access to, or knew, as demonstrated by the information itself or by foundation testimony during a deposition ~~hearing, or trial~~."



5. Paragraph 38--Use of Confidential and Highly Confidential information in responses to common interrogatories, claim construction, expert reports, expert depositions, and at trial; shall incorporate Defendants' proposal.



*Steven C. Mannion*

Honorable Steve Mannion, U.S.M.J.  
United States District Court,  
for the District of New Jersey  
phone: 973-645-3827

5/18/2018 3:26:58 PM

Original: Clerk of the Court  
Hon. Esther Salas, U.S.D.J.  
cc: All parties  
File

# EXHIBIT 6

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

**IN RE: FETZIMA**

C.A. No.: 2:17-CV-10230-ES-SCM

**STIPULATED DISCOVERY CONFIDENTIALITY ORDER**

WHEREAS Forest Laboratories, LLC (f/k/a Forest Laboratories, Inc.),<sup>1</sup> Forest Laboratories Holdings Limited, and Allergan USA, Inc., and Pierre Fabre Medicament S.A.S. (collectively, “Plaintiffs”), and Defendants Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals Private Limited (together, “Amneal”), Aurobindo Pharma USA, Inc. and Aurobindo Pharma Limited (together, “Aurobindo”), MSN Laboratories Private Limited and MSN Pharmaceuticals Inc. (together, “MSN”), Princeton Pharmaceutical Inc. and Solco Healthcare U.S., LLC (together, “Princeton”), Torrent Pharmaceuticals Limited and Torrent Pharma Inc. (together, “Torrent”), West-Ward Pharmaceuticals International Limited and West-Ward Pharmaceuticals Corp. (together, “West-Ward”), and Zydus Pharmaceuticals (USA) Inc. (collectively, “Defendants”) are parties to the above-captioned case (the “Proceeding”); and

WHEREAS, the parties in this Proceeding may exchange discovery material, use or exhibit documents and things during discovery, and elicit testimony containing trade secrets,

---

<sup>1</sup>Pursuant to an internal corporate restructuring, Allergan Sales, LLC is the successor in interest to Forest Laboratories, LLC. Effective January 1, 2018, Forest Laboratories, LLC merged with and into Allergan Sales, LLC, with Allergan Sales, LLC as the surviving entity.

confidential or proprietary research, development, technical, financial or marketing, strategic, customer, or commercial information, personal health information and personal data protected under state or federal privacy laws or other applicable personal data protection laws, as well as other kinds of commercially sensitive information within the meaning of Federal Rule of Civil Procedure 26(c)(1)(G); and

WHEREAS third-parties may produce discovery material containing trade secrets, confidential or proprietary research, development, technical, financial or marketing, strategic, customer, or commercial information, personal health information and personal data protected under state or federal privacy laws or other applicable personal data protection laws in this Proceeding, as well as other kinds of commercially sensitive information within the meaning of Federal Rule of Civil Procedure 26(c)(1)(G); and

WHEREAS the parties and this Court agree that disclosure of such commercially sensitive information poses a substantial risk of harm to the legitimate proprietary interests of the parties and third-parties; and

WHEREAS good cause exists to enter this Discovery Confidentiality Order to preserve the confidentiality of certain documents and information, outline procedures and reasonable restrictions on the disclosure of sensitive materials, and permit discovery to proceed without delay, *see* Fed. R. Civ. P. 26(c), *see also* *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994); and

WHEREAS this Discovery Confidentiality Order provides reasonable restrictions on the disclosure of sensitive materials of a confidential nature; and

WHEREAS all parties agree to the terms of this Discovery Confidentiality Order to protect their confidential documents and information;

THEREFORE, in view of the foregoing and parties' stipulation to the entry of the following Discovery Confidentiality Order pursuant to Fed. R. Civ. P. 26(c) and Local Civil Rule 5.3(b), the Court determined that good cause exists to enter this Order,

IT IS HEREBY STIPULATED AND ORDERED THAT the following Discovery Confidentiality Order governs the disclosure, dissemination, and use of information in this Proceeding:

**I. Designation of Confidential or Highly Confidential Information**

1. Material designated "Confidential" by the producing party constitutes any trade secrets or other research, development, commercial, personnel, financial or marketing information that is non-public and confidential or proprietary, the value of which arises from its secrecy. This material also includes any information protected by the data privacy laws of the European Union or France, and any information relating to an identified or identifiable person residing in the European Economic Area ("EEA"). To the extent required by the data privacy laws of the European Union or France, a party or third-party may redact information that directly or indirectly identifies, or could be used to identify a person residing in the EEA, including but not limited to identification numbers, first and last names, titles, positions, salary and compensation, telephone and electronic records, employment history, contact information, personal life data, professional life data, business transaction data, physical data, physiological data, mental data, economic data, cultural data, and social identity data. Such designation is not an admission by either party that such documents are relevant or admissible in this Proceeding. Notwithstanding the foregoing, or anything else herein, the names of persons reasonably likely to have information related to matters at issue in this litigation will not be redacted.

2. Material designated "Highly Confidential" by the producing party constitutes: (1) material containing such sensitive and confidential information that its disclosure, whether

separately or in conjunction with other information being disclosed, is believed in good faith by the disclosing party to have the potential to cause competitive harm or confer a competitive advantage to others; and (2) any health information protected under state or federal privacy laws, including information that a party is required to maintain in confidence under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”). Accordingly, access to such information will be more restricted. Highly Confidential material includes, but is not limited to, current or future financial documents (such as P&L statements), business strategy, projected future sales, pricing, customer/vendor agreements, revenue, cost, or profit information for the producing party’s products, documents concerning the research and development of the products in suit and any product not in suit, pending patent applications, new drug applications, abbreviated new drug applications, Drug Master Files, and information that could be used to identify an individual’s health information (“individual identifiers”). A party or third-party may redact individual identifiers before producing or disclosing the health information. Individual identifiers include names, initials, postal addresses, telephone numbers, fax numbers, electronic mail addresses, social security numbers, medical record numbers, health plan beneficiary numbers, account numbers, dates of birth, vehicle identifiers or serial numbers, and full face photographic images or other comparable images or identifiers. Highly Confidential information that has been produced and not designated as such will, upon notice, be treated as Highly Confidential under this Discovery Confidentiality Order. Such designation is not an admission by either party that such documents are relevant or admissible in this Proceeding.

3. A party or third-party may designate as “Confidential” or “Highly Confidential,” all or part of any discovery, materials produced or served in this Proceeding, and Court filings (including without limitation, documents and things, pleadings, motions, interrogatory answers,

deposition testimony, and responses to requests for admission), containing sensitive proprietary, personal, business, financial, technical, or other confidential information or know-how protectable under Federal Rule of Civil Procedure 26(c)(1)(G), as set forth in paragraphs 1 and 2 above.

4. A party or third-party shall designate Confidential or Highly Confidential by marking it prominently with “CONFIDENTIAL,” “CONFIDENTIAL—SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER,” “HIGHLY CONFIDENTIAL,” or “HIGHLY CONFIDENTIAL—SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER.” Material that cannot be marked on its face shall be marked by placing the appropriate legend on the container or package of the thing produced or on a tag attached thereto. Each page of an entire multi-page document shall be marked Confidential or Highly Confidential to be treated as such. In addition, each page of every document or thing produced must bear a unique identifying number.

5. A party responding to written interrogatories or requests for admission, or any testimony adduced at a deposition upon written questions that discloses Confidential or Highly Confidential information shall mark the first page of that document near the caption with “CONFIDENTIAL INFORMATION SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER” and/or “HIGHLY CONFIDENTIAL INFORMATION SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER.”

6. Confidential or Highly Confidential information does not include information obtained independently of this Proceeding as to which no obligation of confidentiality applies. Accordingly, nothing in this Order prevents any person from using information designated Confidential or Highly Confidential if such information: (a) was in his or her lawful possession

before receiving the information or document under the provisions of this Order; or (b) was or becomes available to the public through no fault of a receiving party.

7. Nothing in this Order prevents a party or third-party from redacting otherwise discoverable documents or things that contain Confidential or Highly Confidential information irrelevant to this Proceeding or otherwise not discoverable pursuant Federal Rule of Civil Procedure 26(b).

8. Before production, a party or third-party may, to the extent required by the data privacy laws of the European Union or France, redact from all documents, electronic communications, business transaction data, personal electronic files, personally identifiable information described in paragraph 1 for persons residing in the EEA, and personal information.

9. Unless otherwise agreed upon by the parties, deposition transcripts in this Proceeding shall be temporarily designated and treated as Highly Confidential information for up to thirty (30) calendar days after both parties have received a final transcript of the deposition, to give the parties or third-parties an opportunity to properly designate any or all portions of the transcript as Confidential or Highly Confidential. Deposition transcripts or exhibits containing Confidential or Highly Confidential information shall be marked on each page, respectively, "CONFIDENTIAL —SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER" and "HIGHLY CONFIDENTIAL INFORMATION—SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER at page(s) \_\_\_\_." Deponents may review their respective deposition transcripts at any time. Nothing in this paragraph prevents a party from showing depositions transcripts of its own witnesses to its own employees, officers, directors, or agents except that if those deposition transcripts contain Confidential or Highly Confidential



Information of another party, then such information may not be disclosed unless otherwise provided for under this Order.

10. Any material provided for inspection, as opposed to documents produced outright, shall be treated by the inspecting/receiving party as Highly Confidential information pending the copying and delivery of any copies of the same by the producing party. After copies are delivered to the inspecting/receiving party, the information in such documents or things will be treated consistent with any legend on each document or thing. Unless otherwise agreed upon or ordered by this Court, inspection of documents or things by a party shall be conducted only by Outside Counsel eligible under paragraph 14(a) below.

11. Material not designated Confidential or Highly Confidential shall not be subject to this Discovery Confidentiality Order, unless otherwise agreed upon by the parties or ordered by the Court.

## **II. Use of Confidential and Highly Confidential Information**

12. Confidential and Highly Confidential information including all copies, summaries, abstracts, excerpts, indices, and descriptions of such material, shall be: (1) held in confidence by the receiving party; (2) used only by persons permitted access to the information under this Discovery Confidentiality Order; and (3) precluded from use outside of this Proceeding, appeal therefrom, and remands thereto. Nothing in this Order precludes a party from using its own Confidential or Highly Confidential information in any manner it sees fit, without prior consent of any party or the Court. Nothing in this Order restricts any party's counsel from rendering advice to its clients for this Proceeding using Confidential or Highly Confidential information, provided counsel does not disclose any other party's Confidential or Highly Confidential information other than in a manner provided for in this Order.

### **III. Access To Confidential Information**

13. Confidential information may be disclosed only to the following:

- a. Qualified Persons entitled to receive Highly Confidential information as identified and described in paragraph 14 below, and;
- b. Up to two (2) in-house counsel employed by the party (or a subsidiary, parent, and/or affiliate of such party) with responsibilities for managing this Proceeding. Or up to two (2) representatives employed by the party with responsibilities for managing this Proceeding, but only if a party does not have in-house counsel with any responsibility over patent litigation (referred to hereinafter as “representatives”). If a party (or a subsidiary, parent, and/or affiliate of such party) employs in-house counsel or representatives residing in the U.S. with responsibilities for managing intellectual property litigation in the U.S., that party shall only identify such U.S.-based in-house counsel or representatives under this paragraph. In-house counsel or representatives residing outside of the U.S. shall only be identified if a party does not have any in-house counsel or representatives within the U.S. with responsibilities for managing intellectual property litigation in the U.S. The identity of in-house counsel or representatives may be exchanged herein or between Plaintiffs and Defendants. Before such in-house counsel or representatives receive any disclosure as permitted under this DCO of Confidential information, each in-house counsel or representative shall review and agree to be bound by the terms of this DCO by signing Exhibit A. To the extent Confidential Information is provided to in-house counsel or representatives at their offices, that information shall be maintained in a secure fashion and shall not be shared or disseminated. An in-house counsel or representative can be substituted upon written notification via email to all opposing parties along with a completed and signed agreement to be bound by the terms of this DCO (Exhibit A). Subject to the foregoing sentence, any party not now identifying in-house counsel or representatives can do so at a later

date upon written notification via email between Plaintiffs and Defendants pursuant to the provisions set forth in paragraph 17. Subject to the foregoing, the parties designate the following in-house counsel or representatives:

For Plaintiffs:

Forest and Allergan

(1) Ryan Coletti (in-house counsel for Forest Laboratories, LLC n/k/a Allergan Sales, LLC, Forest Laboratories Holdings Limited, and Allergan USA, Inc.)

(2) Shenade Walker (in-house counsel for Forest Laboratories, LLC n/k/a Allergan Sales, LLC, Forest Laboratories Holdings Limited, and Allergan USA, Inc.)

Pierre Fabre

(1) Pierick Rousseau (Intellectual Property Director for Pierre Fabre Medicament S.A.S.)

(2)

For Defendants:

Amneal

(1) TBD

(2) TBD

Aurobindo

(1) TBD

(2) TBD

MSN

(1) TBD

(2) TBD

Princeton

(1) TBD

(2) TBD

Torrent

(1) TBD

(2) TBD

West-Ward

(1) TBD

(2) TBD

Zydus

(1) TBD

(2) TBD

c. In-house counsel or representatives identified in paragraph 13(b) shall not have access to any physical or electronic database containing a party's Confidential or Highly Confidential information.

d. Secretarial and clerical employees of each party who work regularly with such in-house counsel or representatives. The number of in-house counsel or representatives permitted access to Confidential information may be increased by agreement of the parties without leave of the Court, or upon a showing, subject to the approval of the Court, by either party that such modification is necessary.

#### **IV. Access To Highly Confidential Information**

14. Highly Confidential information may be disclosed only to the following "Qualified Persons:"

a. Outside Counsel, defined as the attorneys representing a party in this Proceeding and staff who are from the law firms of Finnegan, Henderson, Farabow, Garrett & Dunner, LLP; Walsh, Pizzi, O'Reilly & Falanga LLP, Rivkin Radler LLP; FisherBroyles, LLP; Richard G. Greco, P.C.; Budd Lerner, P.C.; Winston & Strawn LLP; Stone Conroy LLC; Maddox Edwards PLLC; Hill Wallack LLP; Buchanan Ingersoll & Rooney PC; Merchant & Gould PC, Saiber LLC; and Locke Lord LLP.

b. Up to two (2) in-house counsel employed by each party (or a subsidiary, parent, and/or affiliate of such party) with responsibilities for managing this Proceeding. Or up to two (2) representatives employed by the party with responsibilities for managing this Proceeding, but only if a party does not have in-house counsel with any responsibility over patent litigation (referred to hereinafter as "representatives"). The identity of in-house counsel or

representative may be herein or exchanged between plaintiffs and defendants. Before such in-house counsel or representative receive any disclosure as permitted under this DCO of Highly Confidential information, each in-house counsel or representative shall review and agree to be bound by the terms of this DCO by signing Exhibit A. An in-house counsel or representative can be substituted upon written notification via email to opposing parties along with a completed and signed agreement to be bound by the terms of this DCO (Exhibit A). Subject to the foregoing sentence, any party not now identifying in-house counsel or representatives can do so at a later date upon written notification via email between Plaintiffs and Defendants. Subject to the foregoing, the parties designate the following in-house counsel or representatives:

For Plaintiffs:

Forest and Allergan

- (1) Ryan Coletti (in-house counsel for Forest Laboratories, LLC n/k/a Allergan Sales, LLC, Forest Laboratories Holdings Limited, and Allergan USA, Inc.)
- (2) Shenade Walker (in-house counsel for Forest Laboratories, LLC n/k/a Allergan Sales, LLC, Forest Laboratories Holdings Limited, and Allergan USA, Inc.)

Pierre Fabre

- (1) Pierick Rousseau (Intellectual Property Director for Pierre Fabre Medicament S.A.S.)
- (2) TBD

For Defendants:

Amneal

- (1) TBD
- (2) TBD

Aurobindo

- (1) TBD
- (2) TBD

MSN

- (1) TBD
- (2) TBD

Princeton

- (1) TBD
- (2) TBD

Torrent

- (1) TBD
- (2) TBD

West-Ward

- (1) TBD
- (2) TBD

Zydus

- (1) TBD
- (2) TBD

c. In-house counsel or representative (as defined and identified in Paragraph 14(b)) shall not have access to any physical or electronic database containing a party's Confidential or Highly Confidential information.

d. The individuals identified in paragraph 14(b), but only to Highly Confidential information that is: (1) incorporated in or attached as an exhibit to any discovery response (including any contentions required under the scheduling order and contention interrogatories); (2) used or disclosed in any deposition or attached to any deposition transcript; (3) incorporated in or attached as an exhibit to claim construction exchanges; (4) incorporated in or attached to any document or material filed with the Court; (5) incorporated in or attached to any document or material used in any Court proceeding; (6) incorporated in or attached to an expert report; or (7) documents attached to drafts of categories 1-6 above, consistent with such individuals' duties to review and advise outside counsel on draft work product.

e. Independent litigation support service personnel, including copy vendors, litigation consultants, outside exhibit or demonstrative preparation companies, or litigation study groups retained by a party for litigation support for this Proceeding, provided that such persons or entities: (1) agree to maintain the confidentiality of Confidential and Highly Confidential

information; and (2) are not engaged in the research, development, manufacture, marketing, or sale of pharmaceutical products;

f. Independent consultants or experts assisting Outside Counsel, provided that such consultants or experts: (1) are not current employees of any of the parties in the litigation; and (2) agree to comply with the requirements of this Discovery Confidentiality Order, and sign a copy of Exhibit A to this Discovery Confidentiality Order;

g. The Court and any members of its staff to whom it is necessary to disclose Confidential or Highly Confidential information for the purpose of assisting the Court in this Proceeding, as well as court reporters or typists for the sole purpose of recording, or transcribing testimony, documents, or information relating to this Proceeding;

h. Independent interpreters and translators for the sole purpose of recording, transcribing, or translating testimony or documents relating to this Proceeding.

i. As between Defendants in this case, any document designated “Confidential” may not be disclosed to another Defendant or its representatives and any document designated “Highly Confidential” may not be disclosed to another Defendant or its representatives (as defined in ¶ 14(b)) unless: (1) disclosure is otherwise agreed upon by the Defendants without leave of the Court; or (2) disclosure is necessary upon a showing by any Defendant, and subject to the approval of the Court. As between Plaintiffs and Defendants, any document designated “Confidential” or “Highly Confidential” by a Defendant may not be disclosed by Plaintiffs to the other, non-designating, Defendants unless otherwise agreed upon by the designating Defendant without leave of the Court, or upon Plaintiffs’ showing that such disclosure is necessary and subject to the approval of the Court.

j. Any mediators engaged by the parties, and their support staff.

k. Any person who has been designated as a Rule 30(b)(6) witness by the producing party may be shown the producing party's Highly Confidential information.

l. Any other person (i) agreed to by the parties, as long as such persons comply with the procedures herein and agree to be bound by Exhibit A, or (ii) permitted by the Court.

15. Only opposing outside counsel and opposing identified in-house counsel or representative(s), the deponent, and his or her attorney, shall be allowed to attend any portion of a deposition in which Confidential or Highly Confidential information is used or elicited from the deponent. Counsel for the designating party may request that all persons other than opposing outside counsel and opposing identified in-house counsel or representative(s), the witness, the court reporter, and counsel for the witness (if a third-party witness) leave the deposition room during any portion of a deposition which inquires into matters deemed Confidential or Highly Confidential by the designating party. Failure to leave the deposition room according to the preceding sentence constitutes adequate justification for the designating party's counsel to instruct the witness not to answer the question(s) posed concerning such matters.

16. Nothing in this Order limits a party's examination, at a deposition, hearing, or trial, of persons who are not authorized to receive Confidential or Highly Confidential information under the terms of this Order, so long as such examination concerns only Confidential or Highly Confidential information that the witness authored, received, previously accessed, had access to, or knew, as demonstrated by the information itself or by foundation testimony during a deposition. Nothing in this Order prevents counsel from examining a witness in a good-faith effort to determine whether the witness authored, received, previously accessed, or had knowledge of Confidential or Highly Confidential information.



17. Before disclosing another party's Confidential or Highly Confidential information to the opposing in-house counsel or representative(s) identified under paragraphs 13(b) and 14(b) that in-house counsel or representative(s) shall first provide to the producing party a completed and signed copy of the Certification found in Exhibit A of this Order. Once the producing party has received the requisite documents, the producing party may, within five (5) business days, provide a written objection to the proposed disclosure of its Confidential or Highly Confidential information, including the specific reason(s) for such objection. If a timely written objection is made: (a) the party seeking disclosure shall not disclose the Confidential or Highly Confidential information to the in-house counsel or representative(s), except by further order of the Court or upon agreement by the parties; (b) the parties agree to promptly meet and confer in good faith to resolve the objection; (c) if the parties cannot reach an agreement, the party opposing disclosure may raise the objection with the Court within seven (7) calendar days of the meet and confer. On any motion brought pursuant to this paragraph, the party opposing disclosure shall bear the burden of showing why disclosure of information to that in-house counsel or representative(s) should be precluded. Failure to timely object or file a motion with the Court will act as a waiver of the objection, and disclosure will be permitted to that in-house counsel or representative pursuant to the relevant provision(s) of this Order.

18. Before disclosing another party's Confidential or Highly Confidential information to an outside consultant or expert under paragraph 14(f), a party shall first obtain the signature of the company, firm, group, or person retained on the Certification attached hereto in Exhibit A. A single Certification signed by the company, firm, group, or person shall be sufficient to cover all employees of the company, firm, or group. However, any non-signing employee of the company, firm, or group must be made aware of their obligations under the DCO. Counsel

retaining the person(s) described in subparagraphs 14(f) shall retain the original of each such signed Certification, and exchange with opposing counsel copies of the executed certification within 3 days of its execution.

19. Before disclosing another party's Confidential or Highly Confidential information to any outside consultant or expert under paragraph 14(f), a party shall first provide to the producing party: (a) a completed and signed copy of the Certification found in Exhibit A of this Order; (b) a current resume (*curriculum vitae*) for the consultant or expert; and (c) a list of any other cases in which the consultant or expert has testified as an expert at trial or by deposition within the preceding four (4) years. Once the producing party has received the requisite documents, the producing party may, within five (5) business days, provide a written objection to the proposed disclosure of its Confidential or Highly Confidential information, including the specific reason(s) for such objection. If a timely written objection is made: (a) the party seeking disclosure shall not disclose the Confidential or Highly Confidential information to the consultant or expert, except by further order of the Court or upon agreement by the parties; (b) the parties agree to promptly meet and confer in good faith to resolve the objection; (c) if the parties cannot reach an agreement, the party opposing disclosure may file a motion within seven (7) calendar days of the meet and confer. On any motion brought pursuant to this paragraph, the party opposing disclosure shall bear the burden of showing why disclosure of information to that consultant/expert should be precluded. Failure to timely object or file a motion with the Court will act as a waiver of the objection, and the consultant or expert will be deemed a Qualified Person.

20. Absent consent of the producing parties and/or further order of this Court, any in-house counsel or representative receiving another party's Confidential or any in-house counsel or

representative (as defined in ¶ 14(b)) receiving another party's Highly Confidential information shall not participate in the prosecution of patent applications related to levomilnacipran or levomilnacipran hydrochloride or amend, draft, or otherwise substantively assist, directly or indirectly, in the drafting or amending of patent claims in any reexamination, post-grant review ("PGR") or inter partes review ("IPR") proceeding, claiming pharmaceutical compounds or compositions containing levomilnacipran<sup>2</sup>, including but not limited to methods of using, manufacturing, or processing thereof, and will not participate in or aid in, directly or indirectly, any FDA Citizen Petition related to another party's pharmaceutical compounds or compositions containing levomilnacipran (this shall not preclude participation in responding to any FDA Citizen Petition related to pharmaceutical compounds or composition containing levomilnacipran submitted by another party or third party), for two (2) years after the later of (i) receipt of the Confidential Information or (ii) after a final decision in the suit. For the avoidance of doubt, this paragraph shall not preclude participation in patent opposition, *inter partes review*, post grant review or reexamination proceedings, including any such proceedings before the U.S. Patent and Trademark Office's Patent Trial and Appeal Board, or any foreign patent office, related to levomilnacipran or related products having the same active ingredient, provided that the participation does not include amending, drafting, or otherwise substantively assisting, directly or indirectly, in the drafting or amending of patent claims in any of these proceedings.

21. Without limiting the obligations otherwise imposed by this Order, and absent consent of the producing party, and/or further order of this Court, all Confidential Information and Highly Confidential Information disclosed by another party pursuant to this Order shall be used by a recipient thereof solely for the purposes of prosecuting or defending this litigation and

---

<sup>2</sup>When used herein, "levomilnacipran" means "levomilnacipran and/or levomilnacipran HCl."

not for any business, regulatory, commercial, or competitive purposes. This prohibition does not include legal decision-making responsibilities relating to management of this litigation, or resolution or settlement thereof, including without limitation responsibilities for negotiating or executing an agreement settling litigation, including responsibilities related to any financial terms of such an agreement and responsibilities related to advising on launch dates or providing legal advice regarding product launch.

**V. Challenging or Changing the Designation of Confidential or Highly Confidential Information**

22. A producing party may change a designation of Confidential or Highly Confidential (or withdraw a designation) by notifying counsel for each party in writing. Upon receipt of such notice, the non-producing party shall: (i) not make any further disclosure of the newly designated material except as provided in this Order; (ii) take reasonable steps to notify persons known to have possession of any material with the original designation (or lack of designation) and alert those persons of the effect of such a change in designation; and (iii) promptly retrieve or have destroyed all copies and transcriptions of such originally designated (or undesignated) material from persons known to have possession of such material and who are not Qualified Persons under paragraph 14. With respect to (iii) above, for documents originally lacking a Confidential designation, the copies and transcriptions of such documents should be destroyed or collected from persons or entities not qualified under paragraph 13. The producing party shall promptly and properly mark and provide documents, reflecting the new designation.

23. A party receiving documents or things is not required to challenge the propriety of a Confidential or Highly Confidential information designation (or re-designation) at the time the document or thing is produced, and failure to do so shall not preclude a subsequent challenge

thereto. If a receiving party objects to the producing party's designation, the following procedure shall take effect:

a. The receiving party shall provide the producing party with written notice identifying the documents, things, or information for which a change in designation is sought, and the reasons underlying the request. The producing party may then, within seven (7) calendar days after receipt of the written notice, object in writing to the change in designation sought and specify why the designation is appropriate under this Order.

b. If the producing party submits a timely objection, both parties shall meet and confer to attempt to resolve the dispute without involvement of the Court.

c. If the parties or third-parties cannot reach an agreement concerning the change in designation, the party seeking the change may then file and serve a motion with the Court.

d. The parties or third-parties shall continue to treat the document(s) or thing(s) at issue as Confidential or Highly Confidential information (according to the original designation(s)) until the dispute is resolved by Order of this Court, or by agreement of the parties and/or the third-party.

e. For motions arising out of the designation of any material as Confidential or Highly Confidential information under this Order, the producing party has the burden of justifying the designation.

**VI. Inadvertent Production or Use of Confidential or Highly Confidential Information**

24. Inadvertent production of any document, thing, or information not designated Confidential or Highly Confidential will not waive a later claim of confidentiality or preclude the producing party from designating the material inadvertently produced without the appropriate confidentiality designation as Confidential or Highly Confidential information at a later date.

25. If Confidential or Highly Confidential information is inadvertently used in contravention of this Order, the information shall not lose its confidential status. Counsel shall exercise best efforts and take reasonable measures to protect the confidentiality of the inadvertently used material. If Confidential or Highly Confidential information is inadvertently disclosed to a deposition witness, and the witness has testified concerning that information, the witness may be examined and cross-examined in connection with the document or information disclosed for the remainder of the deposition.

26. If Confidential or Highly Confidential information is disclosed in contravention of this Order, the party responsible for the disclosure shall immediately, but no later than three (3) business days of learning of such disclosure, inform the producing party of all pertinent facts related to such disclosure. The parties shall immediately thereafter use reasonable efforts to return any such Confidential or Highly Confidential information, and obtain a signed Certification (attached hereto as Exhibit A) from each unauthorized person or party receiving Confidential or Highly Confidential information. Nothing in this paragraph prevents the producing party from requesting that the party responsible for the inadvertent disclosure take additional remedial steps and/or applying to the Court for additional relief.

**VII. Inadvertent Production Or Use of Privileged Information**

27. Inadvertently produced information that is subject to a claim of attorney-client privilege, attorney work product immunity, or other legal privilege protecting information will not constitute a waiver (subject matter or otherwise) of any claim of privilege, work product immunity, or other ground for withholding production to which the producing party, third-party, or other person would otherwise be entitled. The protections afforded an inadvertent production include at least those provided in Fed. R. Civ. P. 26(b)(5)(B) and/or Fed. R. Evid. 502.

28. If a producing party makes a written claim of inadvertent production of privileged information to a receiving party, the receiving party shall:

a. upon receipt of the claim, immediately cease further copying, reproducing, or transcribing the inadvertently disclosed information or document; if the inadvertent disclosure is discovered during a deposition, a claim for inadvertent production may be made orally, and upon such oral claim all copies of the requested document must be immediately returned at the deposition; and

b. within five (5) days of receipt of the claim described in paragraph (a) above, destroy or return to the producing party every original, copy, reproduction, or transcription of all such inadvertently produced material in the receiving party's possession and persons to whom the receiving party may have disclosed such information.

29. A claim of inadvertent production based on privilege must be made within two (2) weeks after the material is used openly in the case, e.g., at a court hearing, in a deposition, as an exhibit to a motion, or is referenced in an expert report or pretrial order.

30. Nothing herein prevents a receiving party from challenging the propriety of the attorney-client privilege, work product immunity, or other privilege, or from presenting the information to the Court under seal for a determination of the privilege claim through a written challenge to the Court. If a party challenges the propriety of the attorney-client privilege, work product immunity, or other privilege, that party, notwithstanding the provisions in paragraph 28, may retain one copy of challenged material. The receiving party must preserve the confidentiality of the document or information until the claim is resolved.

#### **VIII. Production or Disclosure of a Third-Party's Information**

31. Any subpoena or other notice to a third-party requesting production of documents must include a copy of this Discovery Confidentiality Order.



32. Documents produced by a third-party pursuant to a subpoena or other request issued by one of the parties (or by Court order), which were not designated Confidential or Highly Confidential, are presumed to contain information requiring no designation under the Discovery Confidentiality Order. All parties to this Proceeding shall handle the third-party's documents and things according to the applicable designations under this Discovery Confidentiality Order. The party issuing the subpoena or other request for documents or things to the third-party shall provide the non-requesting party with copies of any documents produced in response to that subpoena or request.

33. A party in this Proceeding may temporarily withhold production of otherwise discoverable information sought in a discovery request (e.g., interrogatory, request for production, request for admission) if the party is under an obligation to a third-party to withhold such information (e.g., by prior agreement of confidentiality). In such an event (except for information subject to another protective order or confidentiality order by another court), the producing party shall:

- a. timely serve on the requesting party a written objection to the production of the requested information based on its obligation to a third-party to withhold such information;
- b. promptly provide the third-party whose confidentiality interests are implicated with (i) notice of the pending request to disclose the information (and shall copy the requesting party on such notice given to the third-party), and (ii) a copy of this Discovery Confidentiality Order; and
- c. if the third-party does not agree to disclose the information, the requesting party may (i) serve a subpoena on the third-party, provided that the requesting party has not



already done so, or (ii) file a motion to compel production of the requested documents from a party and/or third-party in the appropriate court.

34. A party receiving a subpoena or other request from a third-party seeking disclosure/production of Confidential or Highly Confidential information already disclosed in this Proceeding that the party did not itself produce, shall notify the original producing party of the subpoena or other request immediately, but not later than seven (7) calendar days after service of the subpoena or other request. If the original producing party opposes disclosure of documents sought in the subpoena or other request, the party served with the subpoena shall not disclose the pertinent information until a court has resolved the issue. Absent a court order, production or disclosure of another party's information to a third-party shall not be made until the original producing party has agreed to such production. The original producing party has the burden to oppose the subpoena or other request on the grounds of confidentiality. This paragraph does not apply to information disclosed pursuant to a third-party's subpoena or request for Confidential or Highly Confidential information, if the party receiving the subpoena or request has itself produced the documents or things sought in the subpoena or request, i.e., this paragraph shall not apply to the disclosure of a party's own documents or things.

**IX. Use of Confidential or Highly Confidential Information in Filings and in Open Court**

35. Nothing herein shall be construed to affect the admissibility at trial of any document, testimony, or other evidence.

36. The Clerk of the Court is directed to maintain under seal any pleading, motion, brief, memorandum, exhibit, affidavit, declaration, transcript, response to a discovery request, or other paper filed with the Court in compliance with Local Rule 5.3, which has been designated,

in whole or in part, Confidential or Highly Confidential under this Discovery Confidentiality Order.

37. A party or third-party filing any document, material or information designated by another party as Confidential or Highly Confidential information shall move pursuant to Local Civil Rule 5.3(c) to seal such document, material, or information to prevent public disclosure. The party making such a motion shall also designate any document, material, or information which is the subject of the motion as “confidential materials” pursuant to Local Civil Rule 5.3(c)(3), and take appropriate action necessary to assure that such document, material or information shall remain sealed until the motion is decided.

Should a party fail to properly file documents or materials containing Confidential or Highly Confidential information in accordance with this Order, the Local Civil Rules, or the ECF Policies, any party who in good faith believes that filing under seal is required may file a motion with the Court to request an order sealing such documents or materials.

38. Plaintiffs may not use a Defendant’s produced Confidential or Highly Confidential information in responses to common interrogatories, common claim construction, common expert reports, or common expert depositions. All interrogatories, claim construction, expert reports, and expert depositions containing Confidential or Highly Confidential information unique to a particular Defendant shall be kept separate and not disclosed to another Defendant. To the extent a party contends that certain documents should be made available to another party in the case, the parties agree to make good faith efforts to address such situations on a case-by-case basis and resolve the issue, which may involve the production of redacted copies of the documents in question. Highly Confidential information shall not be used or disclosed in open court except according to Court order, such as an order of the Court sealing the

Court room. The Court will enter further orders as necessary to control the conduct of hearings and trial as it relates to the use of Confidential or Highly Confidential information.

39. Any health information protected under state or federal privacy laws that is disclosed in discovery by a party or third-party to this Proceeding shall not be used or disclosed in open court unless pursuant to Court order, such as an order of the Court sealing the courtroom. The Court will enter further orders as necessary to control the conduct of hearings and trial as it relates to the use of Confidential or Highly Confidential information.

**X. Disposition of Confidential and Highly Confidential Materials After Conclusion of This Proceeding**

40. Upon the final non-appealable termination of this Proceeding, all Confidential or Highly Confidential information received from an opposing or third-party (and all copies and transcriptions thereof), shall be destroyed or returned to the producing party within ninety (90) calendar days. Outside counsel, however, may retain (even if such documents or things contain Confidential or Highly Confidential information) all correspondence, pleadings and exhibits, deposition transcripts and exhibits, expert reports and exhibits, hearing and trial transcripts and exhibits, court-filed documents and exhibits, and all documents and things containing or reflecting attorney work product. Documents and work product retained by Outside Counsel remain subject to the terms of this Order. After ninety (90) calendar days following final non-appealable termination of this Proceeding, no person or entity other than Outside Counsel shall retain any Confidential or Highly Confidential information obtained from another party during the course of the Proceeding, including but not limited to Confidential or Highly Confidential information in the form of notes, recordings, memoranda, summaries or other written materials relating to or containing another party's Confidential or Highly Confidential information.

**XI. Additional Provisions**

41. This Order is binding upon the parties to this Proceeding and signatories to the Certification, including their successor(s) and assigns, and their respective attorneys, agents, representatives, officers, and employees.

42. This Order applies to all information and material produced in this Proceeding, including all information and material produced before the Court executed this Order.

43. The parties agree that the following documents are not discoverable: (a) drafts of expert reports, affidavits, or declarations; (b) counsel's communications with experts, affiants or declarants; and (c) experts', affiants', and declarants' notes and working papers regarding such documents.

44. If any party breaches, or threatens to commit a breach, of any of the provisions of this Order, each non-breaching party or third-party that produced information subject to this Order may seek remedies under law or in equity from the Court, including having the Order specifically enforced (without posting any bond) and/or entering a restraining order or injunction (preliminary or permanent) against the breaching party. It is agreed and acknowledged that, in the event of a breach or threatened breach, the breaching party is not entitled to a presumption that money damages or legal remedies are sufficient or adequate to remedy such a breach.

45. By written agreement of the parties, or upon motion and order of the Court, the terms of this Order may be amended or modified, provided that any stipulated modification concerning the use of Confidential or Highly Confidential information is presented to the Court.

46. This Order is enforceable until amended or superseded by express order of the Court. This Order survives this Proceeding, including any final judgment, appeal, or settlement with respect to Confidential or Highly Confidential information that has not otherwise been disclosed publicly.

47. Nothing in this Order prejudices the right of any party or third-party to oppose production of information for lack of relevance, privilege, or grounds other than confidentiality.

48. In the event a new party is added, substituted, or otherwise brought into this Proceeding, this Discovery Confidentiality Order will bind and inure to the benefit of the new party, subject to the new party's right to seek relief from or modification of this Discovery Confidentiality Order.

49. A legible photocopy of a document may be used as the "original" for all purposes in this Proceeding.

50. Each person or entity receiving any Confidential or Highly Confidential information is subject to the jurisdiction of this Court for proceedings related to the performance under, compliance with, or violation of this Discovery Confidentiality Order.

51. Other Proceedings. By entering this Discovery Confidentiality Order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any party or third-party subject to this Discovery Confidentiality Order who becomes subject to a motion to disclose another party's information designated Confidential or Highly Confidential pursuant to this Discovery Confidentiality Order shall promptly notify the moving party so that party may have an opportunity to appear and be heard on whether that information may be disclosed.

52. In order to expedite the discovery process, until this Discovery Confidentiality Order has been entered by the Court, the parties agree that after counsel for the parties execute this Discovery Confidentiality Order, it will be treated as though it had been "So Ordered."

Respectfully submitted,

*s/Liza M. Walsh*

---

By: Liza M. Walsh  
Eleonore Ofosu-Antwi  
WALSH PIZZI O'REILLY FALANGA LLP  
One Riverfront Plaza  
1037 Raymond Blvd, Suite 600  
Newark, New Jersey 07102  
Tel.: (973) 757-1100

*Of Counsel:*

Howard W. Levine  
Sanya Sukduang  
Courtney S. Casp  
Danielle Duszczyszyn  
FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, LLP  
901 New York Avenue, N.W.  
Washington, D.C. 20001-4413  
(202) 408-4000

*Attorneys for Forest Laboratories, LLC, Forest  
Laboratories Holdings Limited, Allergan USA,  
Inc., and Pierre Fabre Medicament S.A.S.*

*s/Louis H. Weinstein*

---

Louis H. Weinstein  
BUDD LARNER, P.C.  
150 John F. Kennedy Parkway  
Short Hills, New Jersey 07078  
Tel. 973-379-4800  
Fax 973-379-7734  
lweinstein@buddlerner.com

*Attorneys for Defendants  
Prinston Pharmaceutical Inc. and  
Solco Healthcare U.S., LLC*

*s/Rebekah R. Conroy*

---

Rebekah R. Conroy  
STONE CONROY LLC

*s/Gregory D. Miller*

---

Gregory D. Miller  
Gene Y. Kang  
RIVKIN RADLER LLP  
21 Main Street, Suite 158  
Court Plaza South- West Wing  
Hackensack, NJ 07601  
(201) 287-2460

*Of Counsel:*

Gurpreet Singh Walia, M.D.  
FISHERBROYLES, LLP  
100 Duffy Ave, Suite 510  
Hicksville, NY 11801  
(929) 429-5721  
Joseph Schramm, III

FISHERBROYLES, LLP  
100 Overlook Center, Second Floor  
Princeton, NJ 08540  
(856) 733-0220  
Gongjun (Gary) Ji

FISHERBROYLES, LLP  
445 Park Avenue, Ninth Floor  
New York, NY 10022  
(917) 733-3963  
*Attorneys for Defendants*

*Aurobindo Pharma USA, Inc. and  
Aurobindo Pharma Limited*

*s/James S. Richter*

---

James S. Richter  
WINSTON & STRAWN LLP  
200 Park Avenue  
New York, NY 10166  
(212) 294-6700

25A Hanover Road, Suite 301  
Florham Park, NJ 07932  
(973) 400-4181

*Of Counsel:*

Steven Maddox  
Jeremy J. Edwards  
Matthew C. Ruedy  
Kaveh Saba  
MADDOX EDWARDS PLLC  
1900 K Street NW – Suite 725  
Washington, DC 20006  
(202) 830-0707

*Attorneys for Defendants  
Amneal Pharmaceuticals LLC and  
Amneal Pharmaceuticals Private Limited*

*s/Paul B. Sudentas*

---

Paul B. Sudentas  
LOCKE LORD LLP  
Brookfield Place  
200 Vesey Street  
New York, New York 10281

*Of Counsel:*

Michael J. Gaertner  
Andy J. Miller  
Emily L. Savas  
Jonathan B. Turpin  
LOCKE LORD LLP  
111 South Wacker Drive  
Chicago, IL 60606  
(312) 443-0700

*Attorneys for Zydus Pharmaceuticals (USA)  
Inc.*

*Of Counsel:*

Samuel S. Park  
WINSTON & STRAWN LLP  
35 West Wacker Drive  
Chicago, Illinois 60601  
(312) 558-5600  
Charles B. Klein

WINSTON & STRAWN LLP  
1700 K Street, N.W.  
Washington, D.C. 20006  
(202) 282-5000

*Attorneys for Defendants  
West-Ward Pharmaceuticals International  
Limited and West-Ward Pharmaceuticals  
Corp.*

*s/Eric I. Abraham*

---

Eric I. Abraham  
Christina L. Saveriano  
HILL WALLACK LLP  
21 Roszel Road  
Princeton, NJ 08540  
Tel: (609) 924-0808

*Of Counsel:*

Matthew L. Fedowitz  
Erin M. Dunston  
Kimberly E. Coghill  
BUCHANAN INGERSOLL & ROONEY PC  
1737 King Street, Suite 500  
Alexandria, VA 22314  
Tel: (703) 836-6620

Philip L. Hirschhorn  
BUCHANAN INGERSOLL & ROONEY PC  
1290 Avenue of the Americas, 30<sup>th</sup> Floor  
New York, NY 10104-3001  
Tel: (212) 440-4470

*Attorneys for Defendants MSN Laboratories  
Private Limited and MSN Pharmaceuticals,*

*Inc.*

*s/Arnold B. Calmann*

---

Arnold B. Calmann  
Katherine A. Escanlar  
SAIBER LLC  
One Gateway Center  
10th Floor, Suite 1000  
Newark, NJ 07102  
(973) 645-4828

*Of Counsel:*

B. Jefferson Boggs  
MERCHANT & GOULD PC  
1701 Duke Street, Suite 301  
Alexandria, VA 22314  
(703) 684-2500

Christopher J. Sorenson  
MERCHANT & GOULD PC  
3200 IDS Center  
80 S. Eighth Street  
Minneapolis, MN 55402  
(612) 332-5300

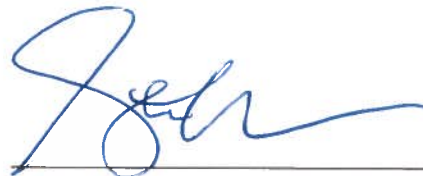
*Attorneys for Defendants Torrent*

*Pharmaceuticals Limited and Torrent Pharma*

*Inc.*

IT IS SO ORDERED

Dated: 7/20/18, ~~2018~~



---

The Honorable Judge Mannion  
UNITED STATES MAGISTRATE JUDGE



## EXHIBIT A

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

**IN RE: FETZIMA**

C.A. No. 2:17-CV-10230-ES-SCM

AGREEMENT TO BE BOUND BY  
DISCOVERY CONFIDENTIALITY  
ORDER

**CERTIFICATION REGARDING DISCOVERY CONFIDENTIALITY ORDER**

1. I, \_\_\_\_\_, have been asked by counsel for Plaintiffs / Defendants [circle one] in the above-captioned matter to review certain confidential or highly confidential documents, or other information subject to the Discovery Confidentiality Order, that has been or will be entered by the District Court for the District of New Jersey in the above-captioned case.

2. My present employer is \_\_\_\_\_ and the  
address of my present employer is \_\_\_\_\_. My present  
occupation or job title is \_\_\_\_\_. My present  
job description is \_\_\_\_\_.

3. I have received a copy of the Discovery Confidentiality Order in this Proceeding.  
I have carefully read and understand its provisions.

4. I will comply with all provisions of the Discovery Confidentiality Order, including but not limited to the following:

a) I will not disclose any information, documents, or things designated as CONFIDENTIAL or HIGHLY CONFIDENTIAL to anyone other than those persons specifically authorized by the Discovery Confidentiality Order.

b) I will not use any Confidential or Highly Confidential information for any purpose other than the above-captioned case.

c) When requested to do so in accordance with the Discovery Confidentiality Order, I will return all materials containing Confidential or Highly Confidential information, and all documents and things that I have prepared relating thereto.

5. I will take reasonable steps to restrict access to any Confidential or Highly Confidential information to only those persons authorized by the Discovery Confidentiality Order to have such access. I will inform any of my employees or staff who encounter Confidential or Highly Confidential information of the terms of the Discovery Confidentiality Order.

6. I understand that my obligations regarding Confidential or Highly Confidential information under the Discovery Confidentiality Order apply equally to copies, summaries, excerpts, transcripts, indices, expert reports, or compilations of information *containing* Confidential or Highly Confidential information, as well as any knowledge or information *derived from* any such information I receive during this action.

7. I understand that if I violate the provisions of the Discovery Confidentiality Order, I will be subject to sanctions by the Court, and that the parties or third-parties that designated the information as Confidential or Highly Confidential may assert other remedies against me.

8. I voluntarily submit to the jurisdiction of the United States District Court for District of New Jersey with respect to the enforcement of the Discovery Confidentiality Order, or with respect to any other order issued by the Court governing the use of confidential information.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Date: \_\_\_\_\_

Signature: \_\_\_\_\_